Risks of Myclobutanil Use to Federally Threatened California Red-legged Frog
(*Rana aurora draytonii*)

Pesticide Effects Determination

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1 Executive Summary

The purpose of this assessment is to evaluate potential direct and indirect effects on the California red-legged frog *(Rana aurora draytonii*) (CRLF) arising from FIFRA regulatory actions regarding use of myclobutanil on agricultural and non-agricultural sites. In addition, this assessment evaluates whether these actions can be expected to result in effects to the species' designated critical habitat. This assessment was completed in accordance with the U.S. Fish and Wildlife Service (USFWS) and National Marine Fisheries Service (NMFS) *Endangered Species Consultation Handbook* (USFWS/NMFS, 1998 and procedures outlined in the Agency's Overview Document (U.S. EPA, 2004).

The CRLF was listed as a threatened species by USFWS in 1996. The species is endemic to California and Baja California (Mexico) and inhabits both coastal and interior mountain ranges. A total of 243 streams or drainages are believed to be currently occupied by the species, with the greatest numbers in Monterey, San Luis Obispo, and Santa Barbara counties (USFWS, 1996) in California.

Myclobutanil is a systemic fungicide. Current labeled uses of myclobutanil include the following food uses: almond, apple, apricot, artichoke, asparagus, beans (succulent), blackberry, boysenberry, canistel, cherry, chrysanthemum garland, cotton, cucurbits (pumpkin, squash, watermelon), currant, dewberry, eggplant, gooseberry, grapes, hops, lettuce (head, leaf), loganberry, mamey (mamme apple), mango, mayhaw (Hawthorn), melons, nectarines, okra, olallie berries, papaya, peach, pepper, peppermint, pimento, plum, prune, raspberry (black, red), sapodilla, sapote white, spearmint, star apple, strawberry, tomato, and youngberry. Non-food/non-feed uses include bluegrass, commercial/industrial lawns, cotton (seed), Douglas Fir (seed orchard, shelter belt), golf course turf, grasses grown for seed, hybrid cottonwood/poplar plantations, loblolly pine (forest), ornamental and shade trees, ornamentals (ground cover, herbaceous plants, lawns and turf, non-flowering plants, sod farm (turf), woody shrubs and vines), residential lawns and slash pine forest. Grapes, apples, almonds, and cherries together make up 80% of all labeled uses of myclobutanil in California.

Myclobutanil is stable to both hydrolysis and photolysis. Myclobutanil degradation is controlled by microbial-mediated transformations. Myclobutanil is moderately persistent to persistent ($DT_{50} > 70$ days) in aerobic soils and persistent in anaerobic soils. The major degradation products observed in the aerobic soil metabolism (ASM) studies are 1,2,4-triazole (maximum 18%), CO_2, a polar degradate (β-4-chlorophenyl-β-cyano-γ-(1H-1,2,4-triazole)-butyric acid and unextractable residues. At the conclusion of the 367 day aerobic soil metabolism study, 29 to 33 percent of the applied radioactivity remained as parent myclobutanil and 13 percent was identified as 1,2,4-triazole. Once the maximum level of 1,2,4-triazole is reached, its decline pattern parallels myclobutanil. Terrestrial field dissipation half-life values range from 92 to 292 days. Because the myclobutanil residues are fairly persistent, the potential to remain in soil is possible, especially when there are multiple applications. Fate studies for 1,2,4-triazole suggest aerobic soil metabolism half-lives ranging from 22 to 375 days.

In addition to 1,2,4-triazole, plant and animal metabolism studies have identified a number of metabolites not identified in the environmental fate studies (soil and water). These metabolites include triazole alanine (TA), triazole acetic acid (TAA) and RH-9090.

Myclobutanil is mobile as indicated by the Freundlich K_{ads} values (from 1.46 to 9.77 mL/g). The degradate (1,2,4-triazole) has lower Freundlich K_{ads} values (0.234 to 0.833 mL/g), suggesting it would be more mobile than the parent compound.

Due to its persistence and mobility, the primary routes of dissipation are thought to be through leaching, runoff, and spray drift. The limited monitoring data for myclobutanil shows detected myclobutanil residues in surface water in California, but not in ground water. Myclobutanil was also found in rainwater in a California watershed, suggesting the occurrence of atmospheric transport.

Since CRLFs exist within aquatic and terrestrial habitats, exposure of the CRLF, its prey and its habitats to myclobutanil are assessed separately for the two habitats. Tier-II aquatic exposure models are used to estimate high-end exposures of myclobutanil in aquatic habitats resulting from runoff and spray drift from different uses. The aquatic assessment quantitatively considers exposure from parent myclobutanil as well as exposure from myclobutanil and the degradation product 1,2,4-triazole. 1,2,4-triazole is a major degradation product that is slowly formed from biodegradation under aerobic and anaerobic conditions in soil. The 1,2,4-triazole's persistence appears to be equal to or less than that of the parent myclobutanil, and it is more mobile. Peak model-estimated environmental concentrations in surface water resulting from different myclobutanil uses range from 2.1 to 61.4 µg/L. These estimates are supplemented with analysis of available California surface water monitoring data from U. S. Geological Survey's National Water Quality Assessment (NAWQA) program and the California Department of Pesticide Regulation. The maximum concentration of parent myclobutanil reported by NAWQA for California surface waters with agricultural watersheds is 0.51 µg/L. This value is approximately 120 times less than the maximum model-estimated environmental concentration. There were no detections of myclobutanil reported in the California Department of Pesticide Regulation surface water database.

To estimate myclobutanil exposures to the terrestrial-phase CRLF, and its potential prey resulting from uses involving myclobutanil applications, the T-REX model is used for foliar, granular and cotton seed treatment uses. The AgDRIFT model is also used to estimate deposition of myclobutanil on terrestrial and aquatic habitats from spray drift. Due to lack of terrestrial plant data for myclobutanil, the TerrPlant model is used for risk description purposes using plant effects data from similar fungicides to estimate myclobutanil exposures to terrestrial-phase CRLF habitat, including plants inhabiting semi-aquatic and dry areas, resulting from uses involving foliar myclobutanil applications. The T-HERPS model is used to allow for further refinement of oral exposures of terrestrial-phase CRLFs (the model allows for an estimation of food intake for poikilotherms using the same basic procedure as T-REX to estimate avian food intake).

The effects determination assessment endpoints for the CRLF include direct toxic effects on the survival, reproduction, and growth of the CRLF itself, as well as indirect effects, such as reduction of the prey base or potential effects to its critical habitat. Direct effects to the CRLF in the aquatic habitat are based on toxicity information for freshwater fish, which are generally used as a surrogate for aquatic-phase amphibians. In the terrestrial habitat, direct effects are based on toxicity information for birds, which are used as a surrogate for terrestrial-phase amphibians. Given that the CRLF's prey items and designated critical habitat requirements in the aquatic habitat are dependant on the availability of freshwater aquatic invertebrates and aquatic plants, toxicity information for these taxonomic groups is also discussed. In the terrestrial habitat, indirect effects due to depletion of prey are assessed by considering effects to terrestrial insects, small terrestrial mammals, and frogs. Indirect effects due to effects to the terrestrial habitat are characterized by available data for terrestrial monocots and dicots.

One of the myclobutanil degradation products observed in environmental fate studies is 1,2,4-triazole. The Office of Pesticide Program's Health Effects Division (HED) has conducted aggregate human health risk assessments for 1,2,4-triazole and triazole conjugates (triazole alanine and triazole acetic acid) derived from conazole fungicides (USEPA. 2006a, 2006b). 1,2,4-triazole and its conjugates are common metabolites to the class of compounds known as the triazoles (a.k.a. triazole-derivative fungicides, T-D fungicides, conazoles). These compounds all have a triazole ring with nitrogen atoms at the 1, 2, and 4 positions.

For the terrestrial exposure assessment, a conservative default foliar dissipation half-life of 35 days is used for all uses of myclobutanil to account for terrestrial exposure to the parent, the primary plant metabolite RH-9090, the 1,2,4-triazole degradate and the triazole conjugates (triazole alanine and triazole acetic acid). Mammalian toxicity data on the degradates and/or a structure-activity analysis on degradates with no toxicity data indicate that they are either equivalent to or less toxic than the parent.

Risk quotients (RQs) are derived as quantitative estimates of potential high-end risk. Acute and chronic RQs are compared to the Agency's levels of concern (LOCs) to identify instances where myclobutanil use within the action area has the potential to adversely affect the CRLF and its designated critical habitat via direct toxicity or indirectly based on direct effects to its food supply (i.e., freshwater invertebrates, algae, fish, frogs, terrestrial invertebrates, and mammals) or habitat (i.e., aquatic plants and terrestrial upland and riparian vegetation). When RQs for each particular type of effect are below LOCs, the pesticide is determined to have "no effect" on the CRLF. Where RQs exceed LOCs, a potential to cause adverse effects is identified, leading to a conclusion of "may affect." If a determination is made that use of myclobutanil use within the action area "may affect" the CRLF or its designated critical habitat, additional information is considered to refine the potential for exposure and effects, and the best available information is used to distinguish those actions that "may affect, but are not likely to adversely affect" (NLAA) from those actions that are "likely to adversely affect" (LAA) the CRLF.

Based on the best available information, the Agency makes a "Likely to Adversely Affect" determination for the CRLF from the use of myclobutanil. Additionally, the Agency has determined that there is the potential for effects to CRLF designated critical habitat from the use of the chemical. The CRLF and/or its critical habitat may be affected for all crops, cotton and turf uses. The terrestrial-phase CRLF may be at risk following consumption of small herbivorous mammals (acute exposure: most crop uses, cotton and turf) and small insects (chronic exposure: cotton and turf uses). Direct effects on the aquatic-phase CRLF are not expected. Indirect effects to the terrestrial-phase CRLF, based on reduction in prey base may occur with terrestrial phase amphibians following acute exposure (most crops, cotton and turf) and chronic exposure (turf and cotton) and with mammals following acute exposure (apple, apricot, cherry, nectarine, peach, hops and turf uses) and chronic exposure (all uses). Indirect effects to the aquatic-phase CRLF, based on reduction in prey base are not expected. Indirect effects to both the aquatic- and terrestrial-phase CRLF based on aquatic and riparian habitat, cover and/or primary productivity may occur due to potential effects on the riparian terrestrial plant community, particularly dicots in semi-aquatic areas (all uses). Direct effects on aquatic plant habitat are not expected. Based on potential effects to the avian/terrestrial-phase amphibians, mammals and terrestrial plants, there is a potential for terrestrial and aquatic habitat effects. A summary of the risk conclusions and effects determinations for the CRLF and its critical habitat is presented in Table 1.1 and 1.2. Further information on the results of the effects determination is included as part of the Risk Description in Section 5.2. Given the LAA determination for the CRLF and potential effects to designated critical habitat, a description of the baseline status and cumulative effects for the CRLF is provided in Attachment 2.

Table 1.1 Effects Determination Summary for Myclobutanil Use and the CRLF

Assessment Endpoint	Effects Determination [1]	Basis for Determination
Survival, growth, and/or reproduction of CRLF individuals	LAA[1]	**Potential for Direct Effects**
		Aquatic-phase (Eggs, Larvae, and Adults): Acute and chronic freshwater fish RQs are below the respective level of concern (LOC) for all uses of myclobutanil.
		Terrestrial-phase (Juveniles and Adults): The acute avian LOC is exceeded at application rates of 0.12 lb a.i./A and above (most crops, cotton and turf). The highest probabilities of an individual effect range from 1 in ~ 3.88E+02 to 1 in ~ 1. The chronic avian LOC is exceeded following uses on cotton (0.06 lb a.i./cwt) and turf at 1.3 lbs a.i./A. Myclobutanil uses overlap CRLF habitat.
		Potential for Indirect Effects
		Aquatic prey items, aquatic habitat, cover and/or primary productivity Acute and chronic freshwater fish RQs are below the respective LOC for all uses

Assessment Endpoint	Effects Determination [1]	Basis for Determination
		of myclobutanil. Acute freshwater invertebrate RQs are below the LOC for all uses of myclobutanil. No chronic freshwater invertebrate studies are available for myclobutanil. Weight of the evidence from RQs based on myclobutanil EECs and toxicity data from 9 other conazole fungicides indicates that minimal impact is expected from chronic exposure to freshwater invertebrates as prey items. Acute RQs for aquatic non-vascular plants for all uses of myclobutanil are below the LOC. No aquatic vascular plant studies are available. Weight of the evidence from RQs based on myclobutanil EECs and toxicity data from 7 other conazole fungicides indicates minimal impact to the CRLF aquatic habitat, cover and/or primary productivity.
		Terrestrial prey items, riparian habitat See description above for direct effects on birds as surrogate for terrestrial phase amphibians. LOCs for listed mammals exceeded following acute exposure at application rates of 0.25 lb a.i./A and above and chronic exposure at application rates of 0.0625 lbs a.i./A and above. Percent effect on mammalian population is estimated to range from 4 – 42% for the myclobutanil uses. Myclobutanil uses overlap CRLF habitat. For terrestrial invertebrates, the honeybee acute contact data show no mortalities at concentration levels up to and including 2836 ppm (highest level tested), which is higher than highest dietary-based EEC for small insects with the use on turf; however, there is some uncertainty for potential mortality. For large invertebrates, there is no concern. Based on the results of the honey bee study and weight of the evidence from open literature studies, indirect impact to the CRLF via effects of myclobutanil on terrestrial invertebrate food items is expected to be minimal. No acceptable terrestrial plant studies are available. RQs based on EECs and toxicity data from 5 other conazole fungicides indicate that most uses may affect terrestrial plants, particularly dicots in semi-aquatic areas. Weight of the evidence from these data, the open literature and incident reports indicates that these effects may have an impact on riparian habitat.

[1] No effect (NE); May affect, but not likely to adversely affect (NLAA); May affect, likely to adversely affect (LAA)

Table 1.2 Effects Determination Summary for Myclobutanil Use and CRLF Critical Habitat Impact Analysis

Assessment Endpoint	Effects Determination	Basis for Determination
Modification of aquatic-phase PCE	Habitat Effects	Acute RQs for aquatic non-vascular plants for all uses of myclobutanil are below the LOC. No aquatic vascular plant studies are available. Weight of the evidence from RQs based on myclobutanil EECs and toxicity data from 7 other conazole fungicides indicates minimal impact to the CRLF aquatic habitat. No acceptable terrestrial plant studies are available. RQs based on EECs and toxicity data from 5 other conazole fungicides indicate that most uses may affect

Assessment Endpoint	Effects Determination	Basis for Determination
		terrestrial plants, particularly dicots in semi-aquatic areas. Weight of the evidence from these data, the open literature and incident reports indicates that these effects may have an impact on riparian habitat. Acute and chronic freshwater fish RQs are below the respective levels of concern (LOC) for all uses of myclobutanil. Indirect effects to the CRLF through effects to its prey in the aquatic habitat (freshwater invertebrates) are expected to be minimal (see table 1.1).
Modification of terrestrial-phase PCE		No acceptable terrestrial plant studies are available. RQs based on EECs and toxicity data from 5 other conazole fungicides indicate that most uses may affect terrestrial plants, particularly dicots in semi-aquatic areas. Weight of the evidence from these data, the open literature and incident reports indicates that these effects may have an impact on riparian habitat. The acute avian LOC is exceeded at application rates of 0.12 lb a.i./A and above (most crops, cotton and turf). The chronic avian LOC is exceeded following uses on cotton (0.06 lb a.i./cwt) and turf at 1.3 lbs a.i./A. LOCs for endangered species exceeded following acute exposure on a dose-basis for many crops and chronic exposure on a dose-basis for all uses and on a dietary-basis for many crops. For terrestrial invertebrates, the weight of the evidence indicates that minimal potential indirect impact to the CRLF via effects on terrestrial invertebrate food items is expected.

Table 1.3 Myclobutanil Use-specific Direct Effects Determinations[1] for the CRLF

Use(s)	Aquatic Habitat		Terrestrial Habitat	
	Acute	Chronic	Acute	Chronic
All uses	NE	NE	-	-
All uses except artichoke, boysenberry, dewberry, youngberry, grape and tomato	-	-	LAA	-
Artichoke, boysenberry, dewberry, youngberry, grape and tomato	-	-	NE	-
Cotton and turf	-	-	-	LAA
All uses except cotton and turf	-	-	-	NE

[1] NE = No effect; NLAA = May affect, but not likely to adversely affect; LAA = Likely to adversely affect

Table 1.4 Myclobutanil Use-specific Indirect Effects Determinations[1] Based on Effects to Prey

Use(s)	Algae	Aquatic Invertebrates		Terrestrial Invertebrates (Acute)	Aquatic-phase frogs and fish		Terrestrial-phase frogs		Small Mammals	
		Acute	Chronic		Acute	Chronic	Acute	Chronic	Acute	Chronic
All uses	NE	NE	NLAA	NLAA	NE	NE	-	-	-	LAA
Footnote 2	-	-	-	-	-	-	LAA	-	-	-
Cotton, turf	-	-	-	-	-	-	-	LAA	-	-
Footnote 3	-	-	-	-	-	-	-	-	LAA	-

1 NE = No effect; NLAA = May affect, not likely to adversely affect; LAA = Likely to adversely affect
2 All uses except artichoke, boysenberry, dewberry, youngberry, grape and tomato
3 Apple, apricot, cherry, nectarine, peach, hops and turf uses

Based on the conclusions of this assessment, a formal consultation with the U. S. Fish and Wildlife Service under Section 7 of the Endangered Species Act should be initiated.

When evaluating the significance of this risk assessment's direct/indirect and habitat effects determinations, it is important to note that pesticide exposures and predicted risks to the species and its resources (i.e., food and habitat) are not expected to be uniform across the action area. In fact, given the assumptions of drift and downstream transport (i.e., attenuation with distance), pesticide exposure and associated risks to the species and its resources are expected to decrease with increasing distance away from the treated field or site of application. Evaluation of the implication of this non-uniform distribution of risk to the species would require information and assessment techniques that are not currently available. Examples of such information and methodology required for this type of analysis would include the following:

- Enhanced information on the density and distribution of CRLF life stages within specific recovery units and/or designated critical habitat within the action area. This information would allow for quantitative extrapolation of the present risk assessment's predictions of individual effects to the proportion of the population extant within geographical areas where those effects are predicted. Furthermore, such population information would allow for a more comprehensive evaluation of the significance of potential resource impairment to individuals of the species.
- Quantitative information on prey base requirements for individual aquatic- and terrestrial-phase frogs. While existing information provides a preliminary picture of the types of food sources utilized by the frog, it does not establish minimal requirements to sustain healthy individuals at varying life stages. Such information could be used to establish biologically relevant thresholds of effects on the prey base, and ultimately establish geographical limits to those effects. This information could be used together with the density data discussed above to characterize the likelihood of adverse effects to individuals.
- Information on population responses of prey base organisms to the pesticide. Currently, methodologies are limited to predicting exposures

and likely levels of direct mortality, growth or reproductive impairment immediately following exposure to the pesticide. The degree to which repeated exposure events and the inherent demographic characteristics of the prey population play into the extent to which prey resources may recover is not predictable. An enhanced understanding of long-term prey responses to pesticide exposure would allow for a more refined determination of the magnitude and duration of resource impairment, and together with the information described above, a more complete prediction of effects to individual frogs and potential effects to critical habitat.

2 Problem Formulation

Problem formulation provides a strategic framework for the risk assessment. By identifying the important components of the problem, it focuses the assessment on the most relevant life history stages, habitat components, chemical properties, exposure routes, and endpoints. The structure of this risk assessment is based on guidance contained in U.S. EPA's Guidance for Ecological Risk Assessment (U.S. EPA 1998), the Services' Endangered Species Consultation Handbook (USFWS/NMFS 1998) and is consistent with procedures and methodology outlined in the Overview Document (U.S. EPA 2004) and reviewed by the U.S. Fish and Wildlife Service and National Marine Fisheries Service (USFWS/NMFS 2004).

2.1 Purpose

The purpose of this endangered species assessment is to evaluate potential direct and indirect effects on individuals of the federally threatened California red-legged frog (*Rana aurora draytonii*) (CRLF) arising from FIFRA regulatory actions regarding use of myclobutanil on almond, asparagus, canistel, cotton, grapes, hops, mamey (mamme apple), okra, peppermint, sapodilla, sapote white, spearmint, star apple, strawberry, and selected crops from the following crop groups: root and tuber; leafy, legume and fruiting vegetables; cucurbits; pome, stone and tropical fruits and berries. Non-food/non-feed uses include bluegrass and grasses grown for seed, various lawn and turf uses, cotton (seed), Douglas Fir (seed orchard, shelter belt), hybrid cottonwood/poplar plantations, loblolly and slash pine forest, ornamental and shade trees, ornamentals, woody shrubs and vines. In addition, this assessment evaluates whether use on these crops is expected to result in effects to the species' designated critical habitat. This ecological risk assessment has been prepared consistent with a settlement agreement in the case Center for Biological Diversity (CBD) vs. EPA et al. (Case No. 02-1580-JSW(JL)) entered in Federal District Court for the Northern District of California on October 20, 2006.

In this assessment, direct and indirect effects to the CRLF and potential effects to its designated critical habitat are evaluated in accordance with the methods described in the Agency's Overview Document (U.S. EPA 2004). Screening level methods include use of standard models such as PRZM-EXAMS, T-REX, Terrplant and AgDRIFT, all of which are described at length in the Overview Document. Additional refinements include an analysis of the usage data, a spatial analysis and the use of the T-HERPS model. Use of such information is consistent with the methodology described in the Overview Document (U.S. EPA 2004), which specifies that "the assessment process may, on a case-by-case basis, incorporate additional methods, models, and lines of evidence that EPA finds technically appropriate for risk management objectives" (Section V, page 31 of U.S. EPA 2004).

In accordance with the Overview Document, provisions of the ESA, and the Services' Endangered Species Consultation Handbook, the assessment of effects associated with registrations of myclobutanil is based on an action area. The action area is the area directly or indirectly affected by the federal action. It is acknowledged that the action area for a national-level FIFRA regulatory decision associated with a use of myclobutanil may potentially involve numerous areas throughout the United States and its Territories. However, for the purposes of this assessment, attention will be focused on relevant sections of the action area including those geographic areas associated with locations of the CRLF and its designated critical habitat within the state of California. As part of the "effects determination," one of the following three conclusions will be reached regarding the potential use of myclobutanil in accordance with current labels:

- "No effect";
- "May affect, but not likely to adversely affect"; or
- "May affect and likely to adversely affect".

Designated critical habitat identifies specific areas that have the physical and biological features, (known as primary constituent elements or PCEs) essential to the conservation of the listed species. The PCEs for CRLFs are aquatic and upland areas where suitable breeding and non-breeding aquatic habitat is located, interspersed with upland foraging and dispersal habitat.

If the results of initial screening-level assessment methods show no direct or indirect effects (no LOC exceedances) upon individual CRLFs or upon the PCEs of the species' designated critical habitat, a "no effect" determination is made for use of myclobutanil as it relates to this species and its designated critical habitat. If, however, potential direct or indirect effects to individual CRLFs are anticipated or effects may impact the PCEs of the CRLF's designated critical habitat, a preliminary "may affect" determination is made for the FIFRA regulatory action regarding myclobutanil.

If a determination is made that use of myclobutanil within the action area(s) associated with the CRLF "may affect" this species or its designated critical habitat, additional information is considered to refine the potential for exposure and for effects to the CRLF and other taxonomic groups upon which these species depend (e.g., aquatic and terrestrial vertebrates and invertebrates, aquatic plants, riparian vegetation, etc.). Additional information, including spatial analysis (to determine the geographical proximity of CRLF habitat and myclobutanil use sites) and further evaluation of the potential impact of myclobutanil on the PCEs is also used to determine whether effects to designated critical habitat may occur. Based on the refined information, the Agency uses the best available information to distinguish those actions that "may affect, but are not likely to adversely affect" from those actions that "may affect and are likely to adversely affect" the CRLF. This information is presented as part of the Risk Characterization in Section 5 of this document.

The Agency believes that the analysis of direct and indirect effects to listed species provides the basis for an analysis of potential effects on the designated critical habitat. Because myclobutanil is expected to directly impact living organisms within the action area (defined in Section 2.7), critical habitat analysis for myclobutanil is limited in a practical sense to those PCEs of critical habitat that are biological or that can be reasonably linked to biologically mediated processes (i.e., the biological resource requirements for the listed species associated with the critical habitat or important physical aspects of the habitat that may be reasonably influenced through biological processes). Activities that may affect critical habitat are those that alter the PCEs and appreciably diminish the value of the habitat. Evaluation of actions related to use of myclobutanil that may alter the PCEs of the CRLF's critical habitat form the basis of the critical habitat impact analysis. Actions that may affect the CRLF's designated critical habitat have been identified by the Services and are discussed further in Section 2.6.

2.2 Scope

The fungicide, myclobutanil is currently registered for both agricultural and non-agricultural uses in the State of California.

The end result of the EPA pesticide registration process (*i.e.*, the FIFRA regulatory action) is an approved product label. The label is a legal document that stipulates how and where a given pesticide may be used. Product labels (also known as end-use labels) describe the formulation type (*e.g.*, liquid or granular), acceptable methods of application, approved use sites, and any restrictions on how applications may be conducted. Thus, the use or potential use of myclobutanil in accordance with the approved product labels for California is "the action" relevant to this ecological risk assessment.

Although current registrations of myclobutanil allow for use nationwide, this ecological risk assessment and effects determination addresses currently registered uses of myclobutanil in portions of the action area that are reasonably assumed to be biologically relevant to the CRLF and its designated critical habitat. Further discussion of the action area for the CRLF and its critical habitat is provided in Section 2.7.

1,2,4-triazole and its conjugates are common metabolites to the triazole class of compounds, including myclobutanil. Only the 1,2,4-triazole degradate was identified in soil and water metabolism studies. The percentage of 1,2,4-triazole reached a high of 18% in the aerobic soil metabolism study with 13 % remaining at the termination of a 367 day study. Because only a limited amount of environmental fate data for 1,2,4-triazole are available, its concentration can not be estimated. For the aquatic exposure assessment, concentrations of parent myclobutanil and the total residues (myclobutanil plus 1,2,4-triazole) are estimated. The total residues for aquatic exposure is conservative if the toxicity of the 1,2,4-triazole is less than or equal to the toxicity of myclobutanil.

For the terrestrial exposure assessment, a conservative default foliar dissipation half-life of 35 days is used to account for terrestrial exposure to the parent, the primary plant metabolite RH-9090, the 1,2,4-triazole degradate and the triazole conjugates (triazole alanine and triazole acetic acid). Crop-specific residue decline data on combined residues of myclobutanil and the primary metabolite RH-9090, provide a range of half-lives from 14 to 26 days. Since no decline data are available for the 1,2,4-triazole and triazole conjugates, toxicity data on the degradates indicate that they are either equivalent to or less toxic than the parent and structure-activity analyses indicate that RH-9090 is likely to be of equivalent toxicity to the parent, the default 35 day half-life is selected for use in estimating terrestrial exposure.

The Agency does not routinely include in its risk assessments an evaluation of mixtures of active ingredients, either those mixtures of multiple active ingredients in product formulations or those in the applicator’s tank. In the case of the product formulations of active ingredients (that is, a registered product containing more than one active ingredient), each active ingredient is subject to an individual risk assessment for regulatory decision regarding the active ingredient on a particular use site. If effects data are available for a formulated product containing more than one active ingredient, they may be used qualitatively or quantitatively in accordance with the Agency’s Overview Document and the Services’ Evaluation Memorandum (U.S., EPA 2004; USFWS/NMFS 2004).

Myclobutanil has registered products that contain multiple active ingredients. Analysis of the available open literature and acute oral mammalian LD_{50} data for multiple active ingredient products relative to the single active ingredient is provided in Appendix A. The results of this analysis show that an assessment based on the toxicity of the single active ingredient of myclobutanil is appropriate. All products with available acute toxicity data had oral LD_{50} values of greater than 5000 mg/kg. Because the active ingredients are not expected to have similar mechanisms of action, metabolites, or toxicokinetic behavior, it is reasonable to conclude that an assumption of dose-addition would be inappropriate. Consequently, an assessment based on the toxicity of myclobutanil is the only reasonable approach that employs the available data to address the potential acute risks of the formulated products.

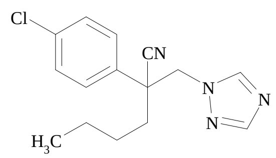
2.3 Previous Assessments

Myclobutanil was registered in the U.S. after 1984 and has not been through the reregistration process. Myclobutanil has been assessed a number of times for new uses including Section 18 assessments. Based on the various past assessments, in general, risk tended to be greatest for freshwater fish (acute), marine/estuarine invertebrates (acute), birds (acute and chronic), and mammals (acute and chronic) depending on the use patterns and application rates. To date, no data on toxicity of myclobutanil to terrestrial plants, aquatic vascular plants, and chronic exposure to invertebrates (freshwater and marine/estuarine) or marine/estuarine fish have been submitted to the Agency for review and so risk has not been assessed quantitatively. Furthermore, certain toxicity data were not available (e.g. chronic exposure to birds and acute exposure to marine/estuarine organisms (fish and invertebrates) and aquatic non-vascular plants) at the time when some uses were assessed; however, that data have been subsequently obtained and used in risk assessments of other uses.

2.4 Stressor Source and Distribution

2.4.1 Physical and Chemical Properties

Selected physical and chemical properties of myclobutanil are summarized below.

Common name:	Myclobutanil
Chemical name:	(CAS): alpha-butyl-alpha (4-chlorophenyl)-1H-1,2-triazole-1-propane-nitrile (IUPAC): (RS)-2-(4-chlorophenyl)-2-(1H-1,2,4-triazol-1-ylmethyl)hexanentrile
Chemical structure:	
Molecular formula	$C_{15}H_{17}ClN_4$
Molecular weight	288.8 g/mol
Physical state:	White crystalline solid
Melting point:	63 to 68 ºC
Solubility:	142 mg/L water @ 25 ºC and pH 7 124 mg/L @ 20 ºC
Vapor pressure	1.49×10^{-06} mm Hg at 25 ºC
Henry's Law constant	3.25×10^{-06} atm m^3/mole @ 25 ºC 1.75×10^{-07} unitless @ 20 ºC
Log Octanol/Water partition coefficient:	2.89 @ pH 7 and 20 ºC
Dissociation Constant, (pKa)	2.3 @ 25 ºC

2.4.2 Environmental Fate Assessment

Available environmental fate parameters of myclobutanil and 1,2,4-triazole degradate are listed in Table 2.1. These data are based on studies that were conducted prior to 1986 before Good Laboratory Practice (GLP) standards (40 CFR 160) and data requirements for registration were promulgated in the Code of Federal Regulations (40 CFR 158). The previously submitted studies have not been re-reviewed, although rate of degradation (i.e., half-life) of myclobutanil in the aerobic soil metabolism study was re-estimated.

Due to its persistence and mobility, the primary routes of dissipation are through leaching, runoff, and spray drift. Myclobutanil has been detected in rain in several agricultural watersheds in California (Vogel et al., 2008); thus, there is also a potential for atmospheric transport. Myclobutanil is stable to hydrolysis and to photolysis. Myclobutanil degradation is controlled by microbial-mediated transformations. Myclobutanil was moderately persistent to persistent (DT_{50} > 70 days) in aerobic soils and persistent in anaerobic soils. The major degradation products observed in the aerobic soil metabolism (ASM) studies were 1,2,4-triazole (maximum 18%), CO_2, a polar degradate (β-4-chlorophenyl-β-cyano-γ-(1H-1,2,4-triazole)-butyric acid; (maximum 9 %), and unextractable residues. At the conclusion of the 367 day ASM study, 29 to 33 percent of the applied radioactivity remained as parent myclobutanil and 13 percent was identified as 1,2,4-triazole.

Myclobutanil degradation in the aerobic soil metabolism (ASM) studies does not appear to follow first-order kinetics based upon visual inspection**,** but follows a “hockey stick” degradation pattern (a rapid initial decline followed by a slower decline), thus the first-order half-life does not accurately describe the decline of myclobutanil residues. The observed (visible inspection) aerobic metabolism DT_{50} value for myclobutanil ranged between 75 and 90 days. The DT_{90} for myclobutanil was not reached during the course of the study (367 days). Once the maximum level of 1,2,4-triazole is reached, its decline pattern parallels myclobutanil. The decline of the combined residues also followed the hockey stick pattern. Myclobutanil photo-degrades with a half-life of approximately 143 days on soil. Thus, myclobutanil residues are fairly persistent. Terrestrial field dissipation half-life values ranged from 92 to 292 days. Generally, half-lives estimated in terrestrial field dissipation studies are less than aerobic soil metabolism studies because they include other dissipation pathways in addition to metabolism. The study with the 292 day terrestrial field dissipation half-life was conducted in California. Leaching was not a significant dissipation pathway. The potential for accumulation in soil and sediment is possible due to the persistence, especially when there are multiple applications. Further discussion is provided in Section 3.2.5, Aquatic Exposure Modeling and Appendix B. In an aerobic soil metabolism study the half-life of 1,2,4-triazole was estimated as 315 days.

Because log K_{ow}s for parent and degradation products are low (log K_{ow}= 2.94), the myclobutanil residues are not expected to bioaccumulate (MRID # 00162541).

Table 2.1 lists the selected physical and environmental fate properties of myclobutanil, along with the major and minor degradate products detected in the submitted environmental fate and transport studies. The submitted study citations can be found in Appendix O.

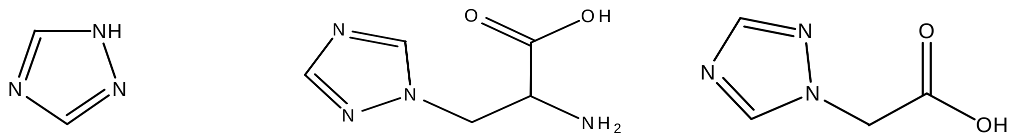
Table 2.1 Summary of Myclobutanil and 1,2,4-triazole Physical and Environmental Fate Properties

Study	Value (units)	Major Degradates *Minor Degradates*	MRID # or Data Source	Study Status
Molecular Weight	288.8 g/mol	-		
Vapor Pressure	1.49×10^{-06} mm Hg at 25 ºC 1.6×10^{-06} mm Hg	-	D190680	-
Henry's Law Constant	3.25×10^{-09} atm m^3/mole @ 25 ºC	-	calculated	-
Laboratory Volatility	No data	-	-	No study submitted
Log K_{ow}	log K_{ow}= 2.94	-	00162541	
Hydrolysis	Stable at pH 5, 7, and 9	-	001416-79	Acceptable
Direct Aqueous Photolysis	Stable	-	40641501 40319801 40528801	Acceptable
Photolysis on soil	143 days	1,2,4-triazole	00164988	Acceptable
Photodegradation in air	No data	-	-	No study submitted
Aerobic Soil Metabolism	198, 244[1] days	1,2,4-triazole, CO_2 and *β-4-chlorophenyl-β-cyano-γ (1H-1,2,4—triazole)-butyric acid*	00164561	Acceptable
Anaerobic Soil Metabolism	Assumed stable, No appreciable degradation in 62 days.	1,2,4-triazole	No MRID	Acceptable
Anaerobic Aquatic Metabolism	No data	-	-	No study submitted
Aerobic Aquatic Metabolism	No data	-	-	No study submitted
Mobility	**Myclobutanil** Freundlich K_{ads} - 1.46, 2.39, 4.44, 7.08, 9.77 mL/g (1/n – 0.89 to 1.02) Koc[2]	**1,2,4-triazole** Freundlich K_{ads} - 0.19 to 3.35 mL/g (1/n – 0.65 to 0.85) Koc[2]	141602 40891501	Acceptable
Terrestrial Field Dissipation	92 to 292 days		164563	Acceptable

[1] Half-lives were recalculated (Appendix C) by EFED (D336254).
[2] Koc not valid, sorption does not appear to be correlated with soil organic carbon (D336254).

The metabolite/degradate 1,2,4-triazole has been detected in plant and animal metabolism studies. However, a number of other degradates or metabolites not identified in soil and water studies have been identified in plant and animal metabolism. These include triazole-analine (TA) and triazole acetic acid (TTA).

The following figures provide the structures of the degradates/metabolites discussed in this assessment.



1,2,4-Triazole (a.k.a. 1,2,4-T; free triazole)	Triazole Alanine (a.k.a. TA)	Triazole Acetic Acid (a.k.a. TAA)
1-H-1,2,4-triazole	α-Amino-1H-1,2,4-triazole-1-propanoic acid	1H-1,2,4-Triazole-1-acetic acid

Chemical structures for 1,2,4-triazole, triazole alanine, and triazole acetic acid

Figure 2.1 Myclobutanil Degradates

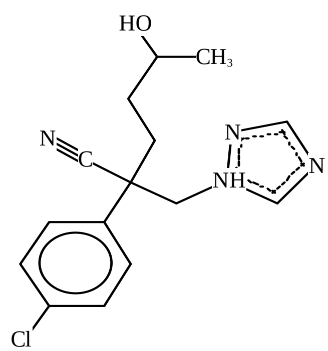


Figure 2.2 Myclobutanil Terrestrial Plant Metabolite

RH-9090 (α-(3-hydroxybutyl)-α-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile)

2.4.3 Environmental Transport Assessment

Potential transport mechanisms include pesticide surface water runoff, spray drift, and secondary drift of volatilized or soil-bound residues leading to deposition onto nearby or more distant ecosystems. Surface water runoff and spray drift are expected to be the major routes of exposure for myclobutanil. The USGS NAWQA Program has detected myclobutanil residues in surface water samples collected in California (USGS, 2009). Myclobutanil has been detected in rain in an agricultural watersheds sampled in California (Vogel et al., 2008). Thus, there appears to a potential for atmospheric transport of myclobutanil.

Myclobutanil is mobile as indicated by the Freundlich K_{ads} values (from 1.46 to 9.77 mL/g) (Table 2.1). The lowest non-sand value is 2.39 mL/g. Desorption coefficients were generally less than the sorption coefficients. The degradate (1,2,4-triaziole) has lower Freundlich K_{ads} values (0.234 to 0.833 mL/g), suggesting it would be more mobile than the parent compound (Table 2.1). The sorption is not strongly correlated to soil organic carbon (matter), thus Koc is not a good measure of mobility for modeling.

A number of studies have documented atmospheric transport and re-deposition of pesticides from the Central Valley to the Sierra Nevada Mountains (Fellers et al., 2004, Sparling et al., 2001, LeNoir et al., 1999, and McConnell et al., 1998). Myclobutanil was detected in rain water in a study partially conducted in California (Vogel et al., 2008). Prevailing winds blow across the Central Valley eastward to the Sierra Nevada Mountains, transporting airborne industrial and agricultural pollutants into the Sierra Nevada ecosystems (Fellers et al*.,* 2004, LeNoir *et al.*, 1999, and McConnell et al*.*, 1998). Several sections of critical habitat for the CLRF are located east of the Central Valley. The magnitude of transport via secondary drift depends on the ability of myclobutanil to be mobilized into air and its eventual removal through wet and dry deposition of gases/particles and photochemical reactions in the atmosphere. Therefore, physicochemical properties of myclobutanil that describe its potential to enter the air from water or soil (*e.g.*, Henry's Law constant and vapor pressure), pesticide use data, modeled estimated concentrations in water and air, and available air monitoring data from the Central Valley and the Sierra Nevadas are considered in evaluating the potential for atmospheric transport of myclobutanil to locations where it could impact the CRLF.

In general, deposition of drifting or volatilized pesticides is expected to be greatest close to the site of application. Computer models of spray drift (AgDRIFT) are used to determine potential exposures to terrestrial organisms via spray drift. The distance of potential impact away from the use sites is determined by the distance required to fall below the chronic LOC for mammals.

2.4.4 Mechanism of Action

Myclobutanil is a triazole fungicide in the conazole class of fungicides which is a systemic fungicide used to control powdery mildew on a number of crops. Myclobutanil appears to be a specific inhibitor of sterol 14-demethylase, which disrupts the ergosterol biosynthesis pathway which is vital to fungal cell wall formation. It is classified as a demethylation inhibitor (DMI) fungicide.

2.4.5 Use Characterization

Analysis of labeled use information is the critical first step in evaluating the federal action. The current label for myclobutanil represents the FIFRA regulatory action; therefore, labeled use and application rates specified on the label form the basis of this assessment. The assessment of use information is critical to the development of the action area and selection of appropriate modeling scenarios and inputs.

Myclobutanil is a triazole fungicide in the conazole class of fungicides. It is a systemic fungicide used to control powdery mildew. It is registered for use on variety of terrestrial food and feed crops and terrestrial non-food crops. Myclobutanil is formulated as a wettable powder (2-40% a.i.) or as an emulsifiable concentrate (1-25% a.i.), granular (<1% a.i.), dust (5% a.i.), dry flowable (60% a.i.), and ready to use (<1% a.i.). Application rates range from 0.04 to 5.0 lbs a.i./acre. Myclobutanil is applied at multiple growth stages (e.g., seed treatment, pre-bloom, bloom, foliar, post-bloom etc.). Application equipment includes hand held devices for both liquids and solids (e.g., trigger spray bottle, aerosol can, shaker jar, high and low volume sprayers), chemigation/irrigation (e.g., sprinkler, solid state), spreader, groundboom, and aircraft. Myclobutanil is also used to treat cotton seed. The formulation for this use is a 25% ai EC. The application rate for cotton is 0.06 lb ai per hundred weight (cwt). Planting depth for cotton seeds varies depending on soil moisture and soil texture. Most labels include the following restrictions/prohibitions: do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark; do not apply directly to water; do not apply when drift is likely to occur; do not apply where runoff is likely to occur. Table 2.2 presents the uses and corresponding application rates and methods of application considered in this assessment.

Table 2.2 Myclobutanil Uses Assessed for the CRLF

Use	Max Single Application Rate (lb ai/A)	Max Number of Applications	Number of Crop Cycles Per Year [a b]	Max Seasonal/Yearly Application Rate (lb ai/A)	Minimum Application Interval
Non-Food/Non-Feed Uses					
Turf Commercial Residential Lawn Golf Course	1.3 (0.03lb/1Kft^2)	4	1	NS	5
Grass grown for seed	0.19	NS	1	NS	14
Cotton (seed)	0.06 lb cwt	NS	NS	NS	NS
Forest Douglas Fir Loblolly Pine	0.25	NS	1	0.6	14
Cottonwood/	0.15	NS	1	0.6	10

Use	Max Single Application Rate (lb ai/A)	Max Number of Applications	Number of Crop Cycles Per Year [a b]	Max Seasonal/Yearly Application Rate (lb ai/A)	Minimum Application Interval
Poplar Plantation					
Ornamentals Shade Trees Groundcover Herbaceous Plant Woody Scrubs/vines	0.26	NS	1	2.0	10
Ornamental Sod Farm	0.6 (0.014lb/1Kft^2)		1	NS	
Slash Pine	0.003 lb ai/gal	NS	1		14
Food/Feed Uses					
Almond	0.2	3/cc 3/yr	1	0.6	7
Apple	0.5	10/cc	1	2.0	7
Apricot	0.5	7/cc	1	1.0	7
Artichokes	0.1	6/cc	1	0.6	14
Asparagus	0.125	6/cc	1	0.75	14
Beans, Green	0.125	4/cc	1	0.5	7
Blackberry	0.125	4/cc 4/yr	1	0.5	10
Boysenberry	0.1	NS	1	0.25	10
Canistel	0.25	8/cc	1	2.0	14
Carrot	0.2	NS	1	0.375	14
Cherry	0.5	7/cc 7/yr	1	1.3	7
Cucurbit Vegetables Balsam Pear Cantaloupe Casaba Honeydew Melon Watermelon Cucumber Pumpkin Squash	0.125	Melon 7/cc 7/yr Other 5 cc	1	0.6	7
Currant	0.125	8/cc	1	1.0	7
Dewberry	0.0625	NS	1	0.25	10
Eggplant	0.125	4/cc	1	0.5	10
Gooseberry	0.125	8/cc	1	1.0	10
Grapes	0.13	6/cc	1	0.6	7
Hops	0.25	4/cc	1	1.0	7
Lettuce	0.125	4/cc	2	0.5	14
Mango	0.25	8/cc	1	2.0	14
Mayhaw	0.25	10/cc	1	2.0	7
Nectarine	0.5	7/yr	1	1.3	7
Okra	0.125	4/cc	1	0.5	10
Papaya	0.25	8/cc	1	2.0	14
Peach	0.5	7/cc 7/yr	1	1.3	7
Pepper	0.125	NS	1	0.5	10
Plum	0.16	7/cc 7/yr	1	1.1	7
Prune	0.15	7/cc 7/yr	1	1.1	7
Raspberry	0.125	4/cc	1	0.25	10
Sapodilla	0.25	8/cc	1	2.0	14
Strawberry	0.125	6/cc	1	0.75	14
Sugar Beet	0.19	NS	1	NS	NS
Tomato	0.1	4/cc	1	0.5	21

Use	Max Single Application Rate (lb ai/A)	Max Number of Applications	Number of Crop Cycles Per Year [a b]	Max Seasonal/Yearly Application Rate (lb ai/A)	Minimum Application Interval
Youngberry	0.0625	NS	1	0.25	10

[a] Number of crop cycles per year for all crops except lettuce as assumed by EFED.
[b] Number of crop cycles for lettuce USEPA 2007 - Memo from Anisha Kaul (BEAD) to Melissa Panger (EFED). Maximum Number of Crop Cycles Per Year in California for Methomyl Use Sites 2/28
NS = Not specified

U.S. Geological Survey (USGS) National Water Quality Assessment Program (NAWQA) data indicate that in 2002, myclobutanil was used on agricultural crops predominantly in California, and Washington, with high usage also in Wisconsin, Michigan and a number northern and mid Atlantic states (Figure 2.3). At that time, the use of myclobutanil on grapes, apples and almonds represented more than 80% of the national use. Based on national usage data compiled by the Biological and Economic Analysis Division (BEAD) primarily from 2001 to 2006, on average, roughly 159,000 pounds of myclobutanil are applied annually to agricultural crops. These data show that usage is highest on grapes, almonds and apples with annual average applications 50,000, 40,000, and 20,000 lbs. a.i. respectively. The crop with the highest average percent crop treated with myclobutanil is artichokes (65%).

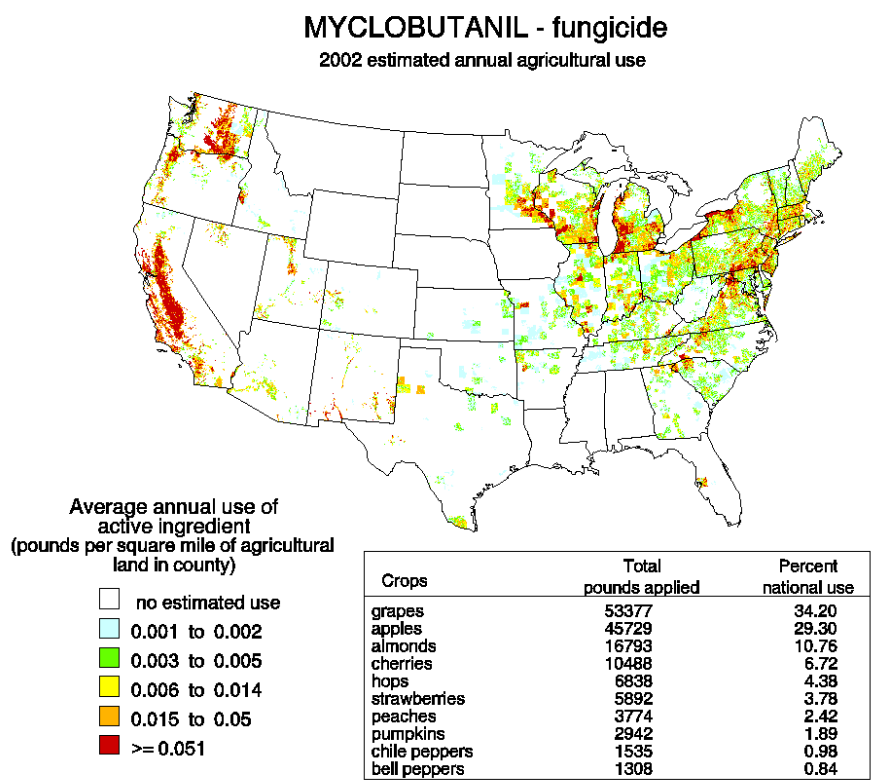


Figure 2.3 Map of Estimated Annual Agricultural Use of Myclobutanil in 2002
http://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=02&map=m5036

Use data specific to California are available from the California Department of Pesticide Regulation's (CDPR) Pesticide Use Reporting (PUR) database, which includes every pesticide application made by professional applicators. BEAD summarized these data, from 1999 to 2006, to the county level by site, pesticide, and unit treated. Based on this analysis, California accounts for approximately 50% of national usage. An average of 81,868 lbs of myclobutanil was applied in California to an average of 763,456 acres per year. Use in California was at a maximum of 95,411 lbs in 2000 and at a minimum of 70,735 lbs in 2006. Usage ranged from 70,000 to 84,000 lbs between 2003 and 2006. From 1999-2006, myclobutanil was used in a total of 54 counties involving 41 different uses. Five counties accounted for 50% of the total lbs applied on average per county [Fresno (14%), Kern (16%), Monterey (11%), San Joaquin (6.5%) and Tulare (10%)]. Each of the other counties used <5% of the total lbs applied. Grapes (table and wine) accounted for approximately 60% of the total lbs applied per year in CA on average. Other major crops include almonds (10%) and strawberries (6%). All other crops accounted for <5% of the total usage on a per crop basis. This analysis may not be entirely representative of current use patterns because labeled uses may have changed since these data were collected, and because it may also include misreporting. A summary of myclobutanil usage for all California use sites is provided below in Table 2.3. Complete data from the BEAD analysis of the CDPR PUR database are presented in Appendix D.

Table 2.3 Summary of California Department of Pesticide Registration (CDPR) Pesticide Use Reporting (PUR) Data from 1999 to 2006 for Currently Registered Myclobutanil Uses

Site Name	Average Pounds All Uses	Avg App Rate All Uses lbs a.i./A	Avg 95th% App Rate lbs a.i./A	Avg 99th% App Rate lbs a.i./A	Avg Max App Rate lbs a.i./A
Almond	426	0.16	0.24	0.41	0.80
Apple	44	0.12	0.21	0.28	0.40
Apricot	15	0.11	0.16	0.19	0.28
Artichoke	103	0.09	0.10	0.13	0.29
Asparagus	46	0.12	0.13	0.13	0.40
Beans, Green	2	0.12	0.14	0.14	0.14
Cantaloupe	0.4	0.09	0.11	0.12	0.12
Cherry	40	0.10	0.14	0.19	0.40
Cucumber	4	0.10	0.11	0.13	0.13
Grape	644	0.10	0.14	0.19	0.41
Melon	17	0.10	0.11	0.20	0.20
Nectarine	40	0.13	0.18	0.21	0.35
Peach	34	0.12	0.21	0.28	0.47
Pepper	48	0.16	0.19	0.21	0.23
Plum	42	0.11	0.14	0.39	0.58
Prune	12	0.12	0.14	0.14	0.21
Pumpkin	8	0.12	0.23	0.29	0.29
Raspberry	7	0.07	0.09	0.17	0.28
Squash	3	0.11	0.12	0.12	0.12
Strawberry	193	0.10	0.14	0.21	0.40
Tomato	38	0.10	0.11	0.21	0.23

Site Name	Average Pounds All Uses	Avg App Rate All Uses lbs a.i./A	Avg 95th% App Rate lbs a.i./A	Avg 99th% App Rate lbs a.i./A	Avg Max App Rate lbs a.i./A
Watermelon	29	0.10	0.12	0.12	0.13
Greenhouse	6	0.11	0.22	0.40	0.55
Landscaping	33	0.46	0.47	0.47	0.47
Rights of Way	0.5	0.07	0.09	0.09	0.09
Turf/Sod	5	1.15	1.36	1.41	1.41

2.5 Assessed Species

The CRLF was federally listed as a threatened species by USFWS effective June 24, 1996 (USFWS 1996). It is one of two subspecies of the red-legged frog and is the largest native frog in the western United States (USFWS 2002). A brief summary of information regarding CRLF distribution, reproduction, diet, and habitat requirements is provided in Sections 2.5.1 through 2.5.4, respectively. Further information on the status, distribution, and life history of and specific threats to the CRLF is provided in Attachment I.

Final critical habitat for the CRLF was designated by USFWS on April 13, 2006 (USFWS 2006; 71 FR 19244-19346). Further information on designated critical habitat for the CRLF is provided in Section 2.6.

2.5.1 Distribution

The CRLF is endemic to California and Baja California (Mexico) and historically inhabited 46 counties in California including the Central Valley and both coastal and interior mountain ranges (USFWS 1996). Its range has been reduced by about 70%, and the species currently resides in 22 counties in California (USFWS 1996). The species has an elevational range of near sea level to 1,500 meters (5,200 feet) (Jennings and Hayes 1994); however, nearly all of the known CRLF populations have been documented below 1,050 meters (3,500 feet) (USFWS 2002).

Populations currently exist along the northern California coast, northern Transverse Ranges (USFWS 2002), foothills of the Sierra Nevada (5-6 populations), and in southern California south of Santa Barbara (two populations) (Fellers 2005a). Relatively larger numbers of CRLFs are located between Marin and Santa Barbara Counties (Jennings and Hayes 1994). A total of 243 streams or drainages are believed to be currently occupied by the species, with the greatest numbers in Monterey, San Luis Obispo, and Santa Barbara counties (USFWS 1996). Occupied drainages or watersheds include all bodies of water that support CRLFs (i.e., streams, creeks, tributaries, associated natural and artificial ponds, and adjacent drainages), and habitats through which CRLFs can move (i.e., riparian vegetation, uplands) (USFWS 2002).

The distribution of CRLFs within California is addressed in this assessment using four categories of location including recovery units, core areas, designated critical habitat, and known occurrences of the CRLF reported in the California Natural Diversity Database

(CNDDB) that are not included within core areas and/or designated critical habitat (see (see Figure 2.4 Recovery Unit, Core Area, Critical Habitat and Occurrence Designations for CRLF). Recovery units, core areas, and other known occurrences of the CRLF from the CNDDB are described in further detail in Attachment I, and designated critical habitat is addressed in Section 2.6. Recovery units are large areas defined at the watershed level that have similar conservation needs and management strategies. The recovery unit is primarily an administrative designation, and land area within the recovery unit boundary is not exclusively CRLF habitat. Core areas are smaller areas within the recovery units that comprise portions of the species' historic and current range and have been determined by USFWS to be important in the preservation of the species. Designated critical habitat is generally contained within the core areas, although a number of critical habitat units are outside the boundaries of core areas, but within the boundaries of the recovery units. Additional information on CRLF occurrences from the CNDDB is used to cover the current range of the species not included in core areas and/or designated critical habitat, but within the recovery units.

Recovery Units

1. Sierra Nevada Foothills and Central Valley
2. North Coast Range Foothills and Western Sacramento River Valley
3. North Coast and North San Francisco Bay
4. South and East San Francisco Bay
5. Central Coast
6. Diablo Range and Salinas Valley
7. Northern Transverse Ranges and Tehachapi Mountains
8. Southern Transverse and Peninsular Ranges

Core Areas

1. Feather River
2. Yuba River- S. Fork Feather River
3. Traverse Creek/ Middle Fork/ American R. Rubicon
4. Cosumnes River
5. South Fork Calaveras River*
6. Tuolumne River*
7. Piney Creek*
8. Cottonwood Creek
9. Putah Creek – Cache Creek*
10. Lake Berryessa Tributaries
11. Upper Sonoma Creek
12. Petaluma Creek – Sonoma Creek
13. Pt. Reyes Peninsula
14. Belvedere Lagoon
15. Jameson Canyon – Lower Napa River
16. East San Francisco Bay
17. Santa Clara Valley
18. South San Francisco Bay
19. Watsonville Slough-Elkhorn Slough
20. Carmel River – Santa Lucia
21. Gablan Range
22. Estero Bay
23. Arroyo Grange River
24. Santa Maria River – Santa Ynez River
25. Sisquoc River
26. Ventura River – Santa Clara River
27. Santa Monica Bay – Venura Coastal Streams
28. Estrella River
29. San Gabriel Mountain*
30. Forks of the Mojave*
31. Santa Ana Mountain*
32. Santa Rosa Plateau
33. San Luis Ray*
34. Sweetwater*
35. Laguna Mountain*

* Core areas that were historically occupied by the California red-legged frog are not included in the map

Figure 2.4 Recovery Unit, Core Area, Critical Habitat and Occurrence Designations for CRLF

Other Known Occurrences from the CNDBB

The CNDDB provides location and natural history information on species found in California. The CNDDB serves as a repository for historical and current species location sightings. Information regarding known occurrences of CRLFs outside of the currently occupied core areas and designated critical habitat is considered in defining the current range of the CRLF. See: http://www.dfg.ca.gov/bdb/html/cnddb_info.html for additional information on the CNDDB.

2.5.2 Reproduction

CRLFs breed primarily in ponds; however, they may also breed in quiescent streams, marshes, and lagoons (Fellers 2005a). According to the Recovery Plan (USFWS 2002), CRLFs breed from November through late April. Peaks in spawning activity vary geographically; Fellers (2005b) reports peak spawning as early as January in parts of coastal central California. Eggs are fertilized as they are being laid. Egg masses are typically attached to emergent vegetation, such as bulrushes (Scirpus spp.) and cattails (Typha spp.) or roots and twigs, and float on or near the surface of the water (Hayes and Miyamoto 1984). Egg masses contain approximately 2000 to 6000 eggs ranging in size between 2 and 2.8 mm (Jennings and Hayes 1994). Embryos hatch 10 to 14 days after fertilization (Fellers 2005a) depending on water temperature. Egg predation is reported to be infrequent and most mortality is associated with the larval stage (particularly through predation by fish); however, predation on eggs by newts has also been reported (Rathburn 1998). Tadpoles require 11 to 28 weeks to metamorphose into juveniles (terrestrial-phase), typically between May and September (Jennings and Hayes 1994, USFWS 2002); tadpoles have been observed to over-winter (delay metamorphosis until the following year) (Fellers 2005b, USFWS 2002). Males reach sexual maturity at 2 years, and females reach sexual maturity at 3 years of age; adults have been reported to live 8 to 10 years (USFWS 2002).

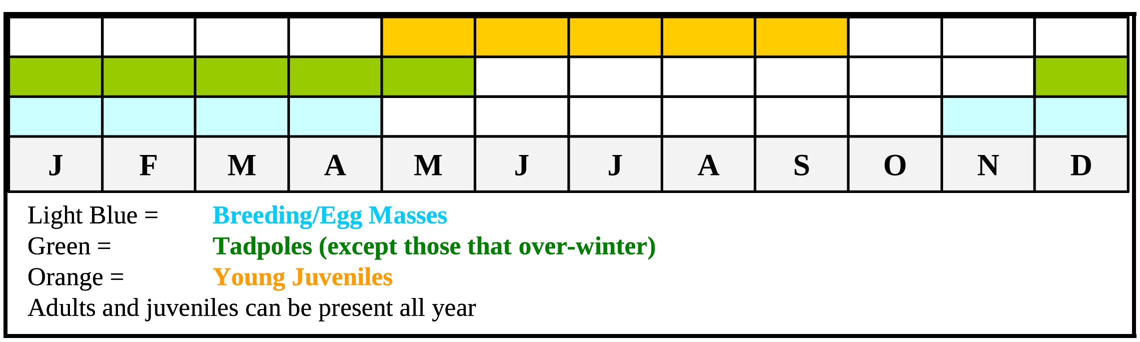


Figure 2.5 CRLF Reproductive Events by Month

2.5.3 Diet

Although the diet of CRLF aquatic-phase larvae (tadpoles) has not been studied specifically, it is assumed that their diet is similar to that of other frog species, with the aquatic phase feeding exclusively in water and consuming diatoms, algae, and detritus (USFWS 2002). Tadpoles filter and entrap suspended algae (Seale and Beckvar, 1980) via mouthparts designed for effective grazing of periphyton (Wassersug, 1984, Kupferberg et al.; 1994; Kupferberg, 1997; Altig and McDiarmid, 1999).

Juvenile and adult CRLFs forage in aquatic and terrestrial habitats, and their diet differs greatly from that of larvae. The main food source for juvenile aquatic- and terrestrial-phase CRLFs is thought to be aquatic and terrestrial invertebrates found along the shoreline and on the water surface. Hayes and Tennant (1985) report, based on a study examining the gut content of 35 juvenile and adult CRLFs, that the species feeds on as many as 42 different invertebrate taxa, including Arachnida, Amphipoda, Isopoda, Insecta, and Mollusca. The most commonly observed prey species were larval alderflies (*Sialis* cf. *californica*), pillbugs (*Armadilliadrium vulgare*), and water striders (*Gerris* sp). The preferred prey species, however, was the sowbug (Hayes and Tennant, 1985). This study suggests that CRLFs forage primarily above water, although the authors note other data reporting that adults also feed under water, are cannibalistic, and consume fish. For larger CRLFs, over 50% of the prey mass may consists of vertebrates such as mice, frogs, and fish, although aquatic and terrestrial invertebrates were the most numerous food items (Hayes and Tennant 1985). For adults, feeding activity takes place primarily at night; for juveniles feeding occurs during the day and at night (Hayes and Tennant 1985).

2.5.4 Habitat

CRLFs require aquatic habitat for breeding, but also use other habitat types including riparian and upland areas throughout their life cycle. CRLF use of their environment varies; they may complete their entire life cycle in a particular habitat or they may utilize multiple habitat types. Overall, populations are most likely to exist where multiple breeding areas are embedded within varying habitats used for dispersal (USFWS 2002). Generally, CRLFs utilize habitat with perennial or near-perennial water (Jennings et al. 1997). Dense vegetation close to water, shading, and water of moderate depth are habitat features that appear especially important for CRLF (Hayes and Jennings 1988). Breeding sites include streams, deep pools, backwaters within streams and creeks, ponds, marshes, sag ponds (land depressions between fault zones that have filled with water), dune ponds, and lagoons. Breeding adults have been found near deep (0.7 m) still or slow moving water surrounded by dense vegetation (USFWS 2002); however, the largest number of tadpoles have been found in shallower pools (0.26 – 0.5 m) (Reis, 1999). Data indicate that CRLFs do not frequently inhabit vernal pools, as conditions in these habitats generally are not suitable (Hayes and Jennings 1988).

CRLFs also frequently breed in artificial impoundments such as stock ponds, although additional research is needed to identify habitat requirements within artificial ponds

(USFWS 2002). Adult CRLFs use dense, shrubby, or emergent vegetation closely associated with deep-water pools bordered with cattails and dense stands of overhanging vegetation (http://www.fws.gov/endangered/features/rl_frog/rlfrog.html#where).

In general, dispersal and habitat use depends on climatic conditions, habitat suitability, and life stage. Adults rely on riparian vegetation for resting, feeding, and dispersal. The foraging quality of the riparian habitat depends on moisture, composition of the plant community, and presence of pools and backwater aquatic areas for breeding. CRLFs can be found living within streams at distances up to 3 km (2 miles) from their breeding site and have been found up to 30 m (100 feet) from water in dense riparian vegetation for up to 77 days (USFWS 2002).

During dry periods, the CRLF is rarely found far from water, although it will sometimes disperse from its breeding habitat to forage and seek other suitable habitat under downed trees or logs, industrial debris, and agricultural features (UWFWS 2002). According to Jennings and Hayes (1994), CRLFs also use small mammal burrows and moist leaf litter as habitat. In addition, CRLFs may also use large cracks in the bottom of dried ponds as refugia; these cracks may provide moisture for individuals avoiding predation and solar exposure (Alvarez 2000).

2.6 Designated Critical Habitat

In a final rule published on April 13, 2006, 34 separate units of critical habitat were designated for the CRLF by USFWS (USFWS 2006; FR 51 19244-19346). A summary of the 34 critical habitat units relative to USFWS-designated recovery units and core areas (previously discussed in Section 2.5.1) is provided in Attachment I.

'Critical habitat' is defined in the ESA as the geographic area occupied by the species at the time of the listing where the physical and biological features necessary for the conservation of the species exist, and there is a need for special management to protect the listed species. It may also include areas outside the occupied area at the time of listing if such areas are 'essential to the conservation of the species.' All designated critical habitat for the CRLF was occupied at the time of listing. Critical habitat receives protection under Section 7 of the ESA (Section 7) through prohibition against destruction or adverse modification with regard to actions carried out, funded, or authorized by a federal Agency. Section 7 requires consultation on federal actions that are likely to result in the destruction or adverse modification of critical habitat.

To be included in a critical habitat designation, the habitat must be 'essential to the conservation of the species.' Critical habitat designations identify, to the extent known using the best scientific and commercial data available, habitat areas that provide essential life cycle needs of the species or areas that contain certain primary constituent elements (PCEs) (as defined in 50 CFR 414.12(b)). PCEs include, but are not limited to, space for individual and population growth and for normal behavior; food, water, air, light, minerals, or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, rearing (or development) of offspring; and habitats that are protected from disturbance or are representative of the historic geographical and ecological distributions of a species. The designated critical habitat areas for the CRLF are considered to have the following PCEs that justify critical habitat designation:

- Breeding aquatic habitat;
- Non-breeding aquatic habitat;
- Upland habitat; and
- Dispersal habitat.

Further description of these habitat types is provided in Attachment I.

Occupied habitat may be included in the critical habitat only if essential features within the habitat may require special management or protection. Therefore, USFWS does not include areas where existing management is sufficient to conserve the species. Critical habitat is designated outside the geographic area presently occupied by the species only when a designation limited to its present range would be inadequate to ensure the conservation of the species. For the CRLF, all designated critical habitat units contain all four of the PCEs, and were occupied by the CRLF at the time of FR listing notice in April 2006. The FR notice designating critical habitat for the CRLF includes a special rule exempting routine ranching activities associated with livestock ranching from incidental take prohibitions. The purpose of this exemption is to promote the conservation of rangelands, which could be beneficial to the CRLF, and to reduce the rate of conversion to other land uses that are incompatible with CRLF conservation. Please see Attachment I for a full explanation on this special rule.

USFWS has established adverse modification standards for designated critical habitat (USFWS 2006). Activities that may destroy or adversely modify critical habitat are those that alter the PCEs and jeopardize the continued existence of the species. Evaluation of actions related to use of myclobutanil that may alter the PCEs of the CRLF's critical habitat form the basis of the critical habitat impact analysis. According to USFWS (2006), activities that may affect critical habitat and therefore result in adverse effects to the CRLF include, but are not limited to the following:

(1) Significant alteration of water chemistry or temperature to levels beyond the tolerances of the CRLF that result in direct or cumulative adverse effects to individuals and their life-cycles.
(2) Alteration of chemical characteristics necessary for normal growth and viability of juvenile and adult CRLFs.
(3) Significant increase in sediment deposition within the stream channel or pond or disturbance of upland foraging and dispersal habitat that could result in elimination or reduction of habitat necessary for the growth and reproduction of the CRLF by increasing the sediment deposition to levels that would adversely affect their ability to complete their life cycles.
(4) Significant alteration of channel/pond morphology or geometry that may lead to changes to the hydrologic functioning of the stream or pond and alter the timing, duration, water flows, and levels that would degrade or eliminate the CRLF

and/or its habitat. Such an effect could also lead to increased sedimentation and degradation in water quality to levels that are beyond the CRLF's tolerances.

(5) Elimination of upland foraging and/or aestivating habitat or dispersal habitat.
(6) Introduction, spread, or augmentation of non-native aquatic species in stream segments or ponds used by the CRLF.
(7) Alteration or elimination of the CRLF's food sources or prey base (also evaluated as indirect effects to the CRLF).

As previously noted in Section 2.1, the Agency believes that the analysis of direct and indirect effects to listed species provides the basis for an analysis of potential effects on the designated critical habitat. Because myclobutanil is expected to directly impact living organisms within the action area, critical habitat analysis for myclobutanil is limited in a practical sense to those PCEs of critical habitat that are biological or that can be reasonably linked to biologically mediated processes.

2.7 Action Area

For listed species assessment purposes, the action area is considered to be the area affected directly or indirectly by the federal action and not merely the immediate area involved in the action (50 CFR 402.02). It is recognized that the overall action area for the national registration of myclobutanil is likely to encompass considerable portions of the United States based on the large array of agricultural uses. However, the scope of this assessment limits consideration of the overall action area to those portions that may be applicable to the protection of the CRLF and its designated critical habitat within the state of California. The Agency's approach to defining the action area under the provisions of the Overview Document (U.S. EPA 2004) considers the results of the risk assessment process to establish boundaries for that action area with the understanding that exposures below the Agency's defined Levels of Concern (LOCs) constitute a no-effect threshold. For the purposes of this assessment, attention will be focused on the footprint of the action (i.e., the area where pesticide application occurs), plus all areas where offsite transport (i.e., spray drift, downstream dilution, etc.) may result in potential exposure within the state of California that exceeds the Agency's LOCs.

Deriving the geographical extent of this portion of the action area is based on consideration of the types of effects that myclobutanil may be expected to have on the environment, the exposure levels to myclobutanil that are associated with those effects, and the best available information concerning the use of myclobutanil and its fate and transport within the state of California. Specific measures of ecological effect that define the action area include any direct and indirect toxic effect and any potential effects to critical habitat, including reduction in survival, growth, and fecundity as well as the full suite of sublethal effects available in the effects literature. Therefore, the action area extends to a point where environmental exposures are below any measured lethal or sublethal effect threshold for any biological entity at the whole organism, organ, tissue, and cellular level of organization. In situations where it is not possible to determine the threshold for an observed effect, the action area is not spatially limited and is assumed to be the entire state of California.

The definition of action area requires a stepwise approach that begins with an understanding of the federal action. The federal action is defined by the currently labeled uses for myclobutanil. An analysis of labeled uses and review of available product labels was completed. Several of the currently labeled uses are special local needs (SLN) uses or are restricted to specific states and are excluded from this assessment. In addition, a distinction has been made between food use crops and those that are non-food/non-agricultural uses. For those uses relevant to the CRLF, the analysis indicates that, for myclobutanil, the following agricultural uses are considered as part of the federal action evaluated in this assessment:

- almond, apple, apricot, artichoke, asparagus, blackberry, boysenberry, canistel, carrot, cherry, cucurbit vegetables (e.g. melons, squash), currant, dewberry, eggplant, gooseberry, green beans, grapes, hops, lettuce, mango, mayhaw, nectarine, okra, papaya, peach, pepper, plum, prune, raspberry, sapodilla, strawberry, sugar beet, tomato, and youngberry.

In addition, the following non-food and non-agricultural uses are considered:

- commercial, residential and golf course turf, ornamental and herbaceous plants, grass grown for seed, cotton seed, ornamental sod farms, Douglas fir and loblolly pine and slash pine forests, and hybrid cotton wood/poplar plantations.

Following a determination of the assessed uses, an evaluation of the potential "footprint" of myclobutanil use patterns (i.e., the area where pesticide application occurs) is determined. This "footprint" represents the initial area of concern, based on an analysis of available land cover data for the state of California. The initial area of concern is defined as all land cover types and the stream reaches within the land cover areas that represent the labeled uses described above. A map representing all the land cover types that make up the initial area of concern for myclobutanil is presented in Figure 2.6.

The following land cover types were used for myclobutanil cultivated crops, forest, orchards and vineyards and turf. More information regarding which specific uses are represented for each land cover types can be found in Appendix E.

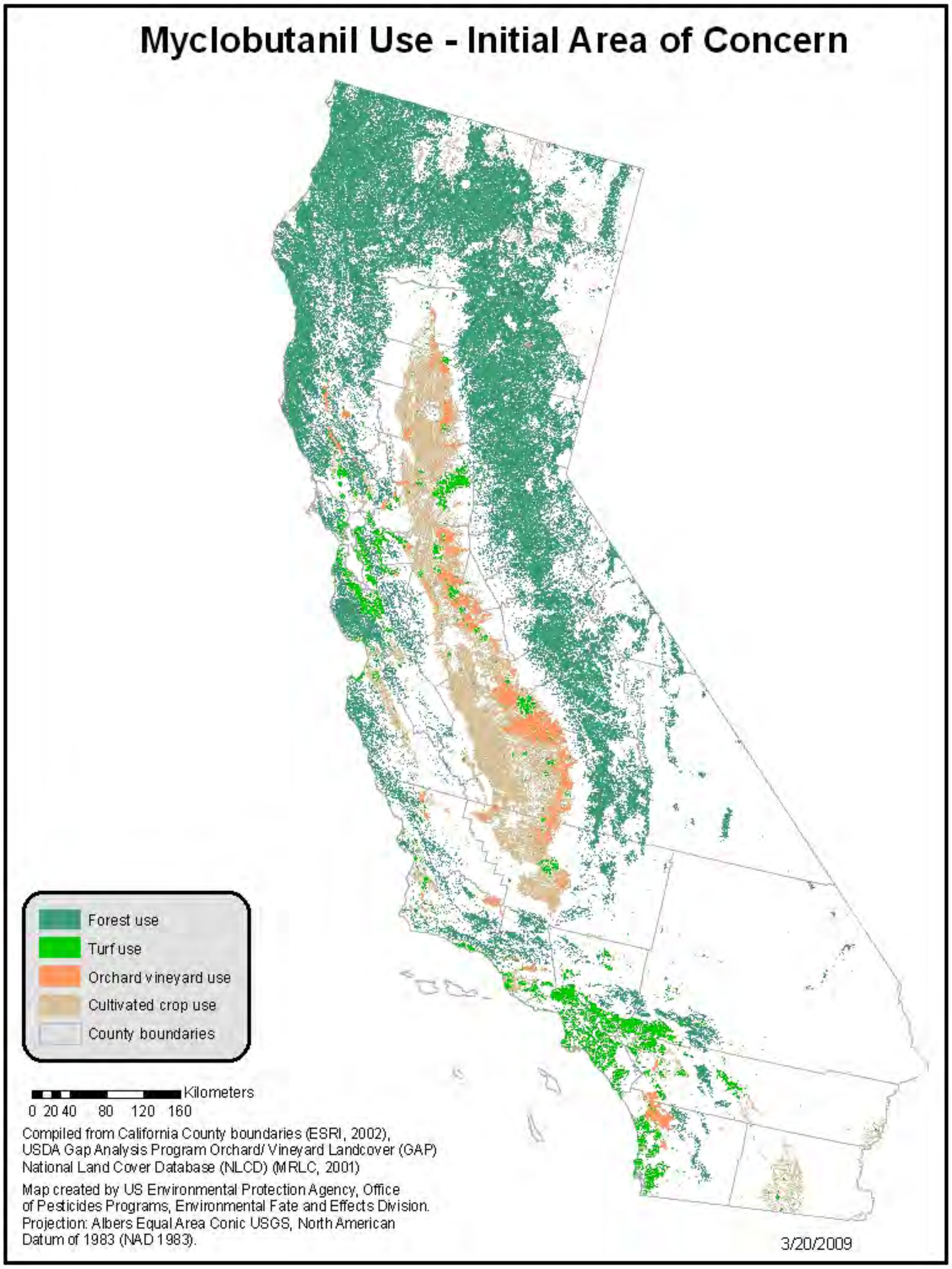


Figure 2.6 Initial Area of Concern of "footprint" of potential use for myclobutanil

As previously discussed, the action area is defined by the most sensitive measure of direct and indirect ecological toxic effects including reduction in survival, growth, reproduction, and the entire suite of sublethal effects from valid, peer-reviewed studies. Due to the lack of a defined dose at which there were no effects and the presence of sublethal effects (lethargy and anorexia) and mortalities at all dose levels in an avian acute oral toxicity study (MRID 00144286), the spatial extent of the action area (i.e., the boundary where exposures and potential effects are less than the Agency's LOC) for myclobutanil cannot be determined. Therefore, it is assumed that the action area encompasses the entire state of California, regardless of the spatial extent (i.e., initial area of concern or footprint) of the pesticide use(s).

2.8 Assessment Endpoints and Measures of Ecological Effect

Assessment endpoints are defined as "explicit expressions of the actual environmental value that is to be protected."[1] Selection of the assessment endpoints is based on valued entities (e.g., CRLF, organisms important in the life cycle of the CRLF, and the PCEs of its designated critical habitat), the ecosystems potentially at risk (e.g., waterbodies, riparian vegetation, and upland and dispersal habitats), the migration pathways of myclobutanil (e.g., runoff, spray drift, etc.), and the routes by which ecological receptors are exposed to myclobutanil (e.g., direct contact, etc.).

2.8.1 Assessment Endpoints for the CRLF

Assessment endpoints for the CRLF include direct toxic effects on the survival, reproduction, and growth of the CRLF, as well as indirect effects, such as reduction of the prey base or effects to its habitat. In addition, potential effects to critical habitat are assessed by evaluating potential effects to PCEs, which are components of the habitat areas that provide essential life cycle needs of the CRLF. Each assessment endpoint requires one or more "measures of ecological effect," defined as changes in the attributes of an assessment endpoint or changes in a surrogate entity or attribute in response to exposure to a pesticide. Specific measures of ecological effect are generally evaluated based on acute and chronic toxicity information from registrant-submitted guideline tests that are performed on a limited number of organisms. Additional ecological effects data from the open literature are also considered. It should be noted that assessment endpoints are limited to direct and indirect effects associated with survival, growth, and fecundity, and do not include the full suite of sublethal effects used to define the action area. According the Overview Document (USEPA 2004), the Agency relies on acute and chronic effects endpoints that are either direct measures of impairment of survival, growth, or fecundity or endpoints for which there is a scientifically robust, peer reviewed relationship that can quantify the impact of the measured effect endpoint on the assessment endpoints of survival, growth, and fecundity.

A complete discussion of all the toxicity data available for this risk assessment, including resulting measures of ecological effect selected for each taxonomic group of concern, is

[1] U.S. EPA (1992). *Framework for Ecological Risk Assessment.* EPA/630/R-92/001.

included in Section 4.0 of this document. A summary of the assessment endpoints and measures of ecological effect selected to characterize potential assessed direct and indirect CRLF risks associated with exposure to myclobutanil is provided in Table 2.4.

Table 2.4 Assessment Endpoints and Measures of Ecological Effects

Assessment Endpoint	Measures of Ecological Effects[2]
Aquatic-Phase CRLF (Eggs, larvae, juveniles, and adults)[a]	
Direct Effects	
1. Survival, growth, and reproduction of CRLF	1a. Bluegill sunfish acute LC_{50} 1b. Fathead minnow chronic NOAEC
Indirect Effects and Critical Habitat Effects	
2. Survival, growth, and reproduction of CRLF individuals via indirect effects on aquatic prey food supply (*i.e.*, fish, freshwater invertebrates, non-vascular plants)	2a. Bluegill sunfish acute LC_{50}, water flea acute LC_{50}, green algae EC_{50}. 2b. Fathead minnow chronic NOAEC; no freshwater invertebrate chronic study available; daphnia chronic NOAEC from 9 similar conazole fungicides.
3. Survival, growth, and reproduction of CRLF individuals via indirect effects on habitat, cover, food supply, and/or primary productivity (*i.e.*, aquatic plant community)	3a. No vascular plant study available; duckweed EC_{50} data from 7 similar conazole fungicides. 3b. Green algae EC_{50}.
4. Survival, growth, and reproduction of CRLF individuals via effects to riparian vegetation	4a. No seedling emergence or vegetative vigor studies available; terrestrial plant EC_{25} and NOAEC data from 5 similar conazole fungicides 4b. No seedling emergence or vegetative vigor studies available; terrestrial plant EC_{25} and NOAEC data from 5 similar conazole fungicides
Terrestrial-Phase CRLF (Juveniles and adults)	
Direct Effects	
5. Survival, growth, and reproduction of CRLF individuals via direct effects on terrestrial phase adults and juveniles	5a. Bobwhite quail LD_{50} and Mallard duck LC_{50}[b] 5b. Bobwhite quail chronic NOAEC
Indirect Effects and Critical Habitat Effects	
6. Survival, growth, and reproduction of CRLF individuals via effects on terrestrial prey (*i.e.*,terrestrial invertebrates, small mammals , and frogs)	6a. Honey bee acute EC_{50} and mouse acute LD_{50} 6b. Rat chronic NOAEC (no chronic invertebrate study available)
7. Survival, growth, and reproduction of CRLF individuals via indirect effects on habitat (*i.e.*, riparian and upland vegetation)	7a. No seedling emergence or vegetative vigor studies available; terrestrial plant EC_{25} and NOAEC data from 5 similar conazole fungicides 7b. No seedling emergence or vegetative vigor studies available; terrestrial plant EC_{25} and NOAEC data from 5 similar conazole fungicides

[a] Adult frogs are no longer in the "aquatic phase" of the amphibian life cycle; however, submerged adult frogs are considered "aquatic" for the purposes of this assessment because exposure pathways in the water are considerably different that exposure pathways on land.
[b] Birds are used as surrogates for terrestrial phase amphibians.

[2] All registrant-submitted and open literature toxicity data reviewed for this assessment are included in Appendix A.

2.8.2 Assessment Endpoints for Designated Critical Habitat

As previously discussed, designated critical habitat is assessed to evaluate actions related to the use of myclobutanil that may alter the PCEs of the CRLF's critical habitat. PCEs for the CRLF were previously described in Section 2.6. Actions that may modify critical habitat are those that alter the PCEs and jeopardize the continued existence of the CRLF. Therefore, these actions are identified as assessment endpoints. It should be noted that evaluation of PCEs as assessment endpoints is limited to those of a biological nature (i.e., the biological resource requirements for the listed species associated with the critical habitat) and those for which myclobutanil effects data are available. Effects to the critical habitat of the CRLF include, but are not limited to those listed in Section 2.6.

Measures of such possible effects by labeled use of myclobutanil on critical habitat of the CRLF are described in Table 2.5. Some components of these PCEs are associated with physical abiotic features (e.g., presence and/or depth of a water body, or distance between two sites), which are not expected to be measurably altered by use of pesticides. Assessment endpoints used for the analysis of designated critical habitat are based on the adverse modification standard established by USFWS (2006).

Table 2.5 Summary of Assessment Endpoints and Measures of Ecological Effect for Primary Constituent Elements of Designated Critical Habitat[a]

Assessment Endpoint	Measures of Ecological Effect
Aquatic-Phase CRLF PCEs (Aquatic Breeding Habitat and Aquatic Non-Breeding Habitat)	
Alteration of channel/pond morphology or geometry and/or increase in sediment deposition within the stream channel or pond: aquatic habitat (including riparian vegetation) provides for shelter, foraging, predator avoidance, and aquatic dispersal for juvenile and adult CRLFs.	a. Green algae EC_{50}. No vascular plant study available; duckweed EC_{50} data from 7 similar conazole fungicides. b. No seedling emergence or vegetative vigor studies available; terrestrial plant EC_{25} and NOAEC data from 5 similar conazole fungicides c. No seedling emergence or vegetative vigor studies available; terrestrial plant EC_{25} and NOAEC data from 5 similar conazole fungicides
Alteration in water chemistry/quality including temperature, turbidity, and oxygen content necessary for normal growth and viability of juvenile and adult CRLFs and their food source.	a. Green algae EC_{50}. No vascular plant study available; duckweed EC_{50} data from 7 similar conazole fungicides. b. No seedling emergence or vegetative vigor studies available; terrestrial plant EC_{25} and NOAEC data from 5 similar conazole fungicides c. No seedling emergence or vegetative vigor studies available; terrestrial plant EC_{25} and NOAEC data from 5 similar conazole fungicides
Alteration of other chemical characteristics necessary for normal growth and viability of CRLFs and their food source.	a. Bluegill sunfish acute LC_{50} and water flea acute LC_{50}. b. Fathead minnow chronic NOAEC. No freshwater invertebrate chronic study available; daphnia chronic NOAEC from 9 similar conazole fungicides.
Reduction and/or modification of aquatic-based food sources for pre-metamorphs (*e.g.*, algae)	a. Green algae EC_{50}. No vascular plant study available; duckweed EC_{50} data from 7 similar conazole fungicides.
Terrestrial-Phase CRLF PCEs (Upland Habitat and Dispersal Habitat)	
Elimination and/or disturbance of upland habitat; ability of habitat to support food source of CRLFs: Upland areas within 200 ft of the edge of the riparian vegetation or dripline surrounding aquatic and riparian habitat that are comprised of grasslands, woodlands, and/or wetland/riparian plant species that provides the CRLF shelter, forage, and predator avoidance	a. No seedling emergence or vegetative vigor studies available; terrestrial plant EC_{25} and NOAEC data from 5 similar conazole fungicides. b. No seedling emergence or vegetative vigor studies available; terrestrial plant EC_{25} and NOAEC data from 5 similar conazole fungicides. c. Bobwhite quail LD_{50}, mallard duck LC_{50}, bobwhite quail chronic NOAEC, honey bee acute EC_{50}, mouse acute LD_{50}, rat chronic NOAEC (no chronic invertebrate study available), bluegill sunfish acute LC_{50} and fathead minnow chronic NOAEC.
Elimination and/or disturbance of dispersal habitat: Upland or riparian dispersal habitat within designated units and between occupied locations within 0.7 mi of each other that allow for movement between sites including both natural and altered sites which do not contain barriers to dispersal	
Reduction and/or modification of food sources for terrestrial phase juveniles and adults	
Alteration of chemical characteristics necessary for normal growth and viability of juvenile and adult CRLFs and their food source.	

[a] Physico-chemical water quality parameters such as salinity, pH, and hardness are not evaluated because these processes are not biologically mediated and, therefore, are not relevant to the endpoints included in this assessment.

2.9 Conceptual Model

2.9.1 Risk Hypotheses

Risk hypotheses are specific assumptions about potential adverse effects (i.e., changes in assessment endpoints) and may be based on theory and logic, empirical data, mathematical models, or probability models (U.S. EPA, 1998). For this assessment, the risk is stressor-linked, where the stressor is the release of myclobutanil to the environment. The following risk hypotheses are presumed for this endangered species assessment:

The labeled use of myclobutanil within the action area may:

- directly affect the CRLF by causing mortality or by adversely affecting growth or fecundity;
- indirectly affect the CRLF by reducing or changing the composition of food supply;
- indirectly affect the CRLF or affect designated critical habitat by reducing or changing the composition of the aquatic plant community in the ponds and streams comprising the species' current range and designated critical habitat, thus affecting primary productivity and/or cover;
- indirectly affect the CRLF or affect designated critical habitat by reducing or changing the composition of the terrestrial plant community (i.e., riparian habitat) required to maintain acceptable water quality and habitat in the ponds and streams comprising the species' current range and designated critical habitat;
- affect the designated critical habitat of the CRLF by reducing or changing breeding and non-breeding aquatic habitat (via modification of water quality parameters, habitat morphology, and/or sedimentation);
- affect the designated critical habitat of the CRLF by reducing the food supply required for normal growth and viability of juvenile and adult CRLFs;
- affect the designated critical habitat of the CRLF by reducing or changing upland habitat within 200 ft of the edge of the riparian vegetation necessary for shelter, foraging, and predator avoidance;
- affect the designated critical habitat of the CRLF by reducing or changing dispersal habitat within designated units and between occupied locations within 0.7 mi of each other that allow for movement between sites including both natural and altered sites which do not contain barriers to dispersal;
- affect the designated critical habitat of the CRLF by altering chemical characteristics necessary for normal growth and viability of juvenile and adult CRLFs.

2.9.2 Diagram

The conceptual model is a graphic representation of the structure of the risk assessment. It specifies the stressor (myclobutanil) release mechanisms, biological receptor types, and effects endpoints of potential concern. The conceptual models for terrestrial and aquatic exposures are shown in Figure 2.7 and Figure 2.8, respectively, which include the conceptual models for the aquatic and terrestrial PCE components of critical habitat. Exposure routes shown in dashed lines are not quantitatively considered because the contribution of those potential exposure routes to potential effects on the CRLF and designated critical habitat is expected to be negligible.

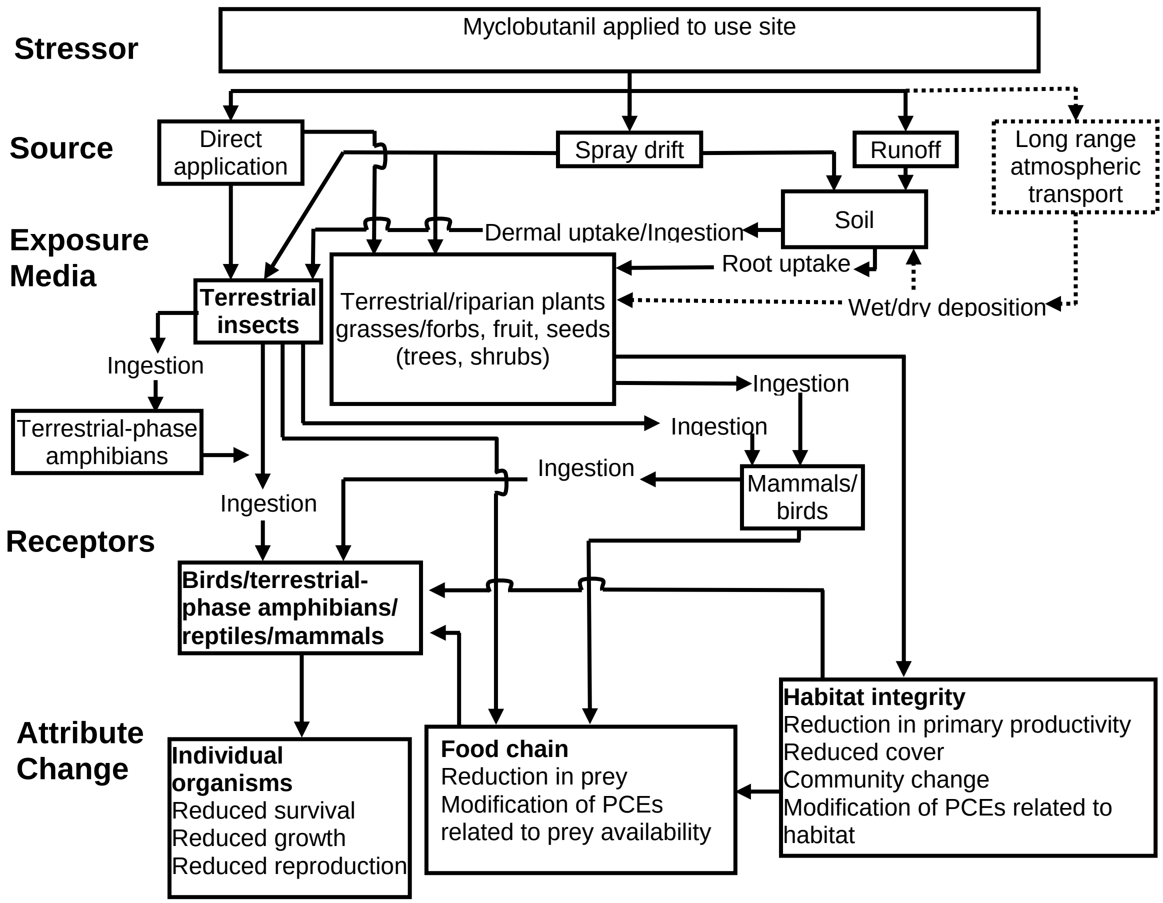
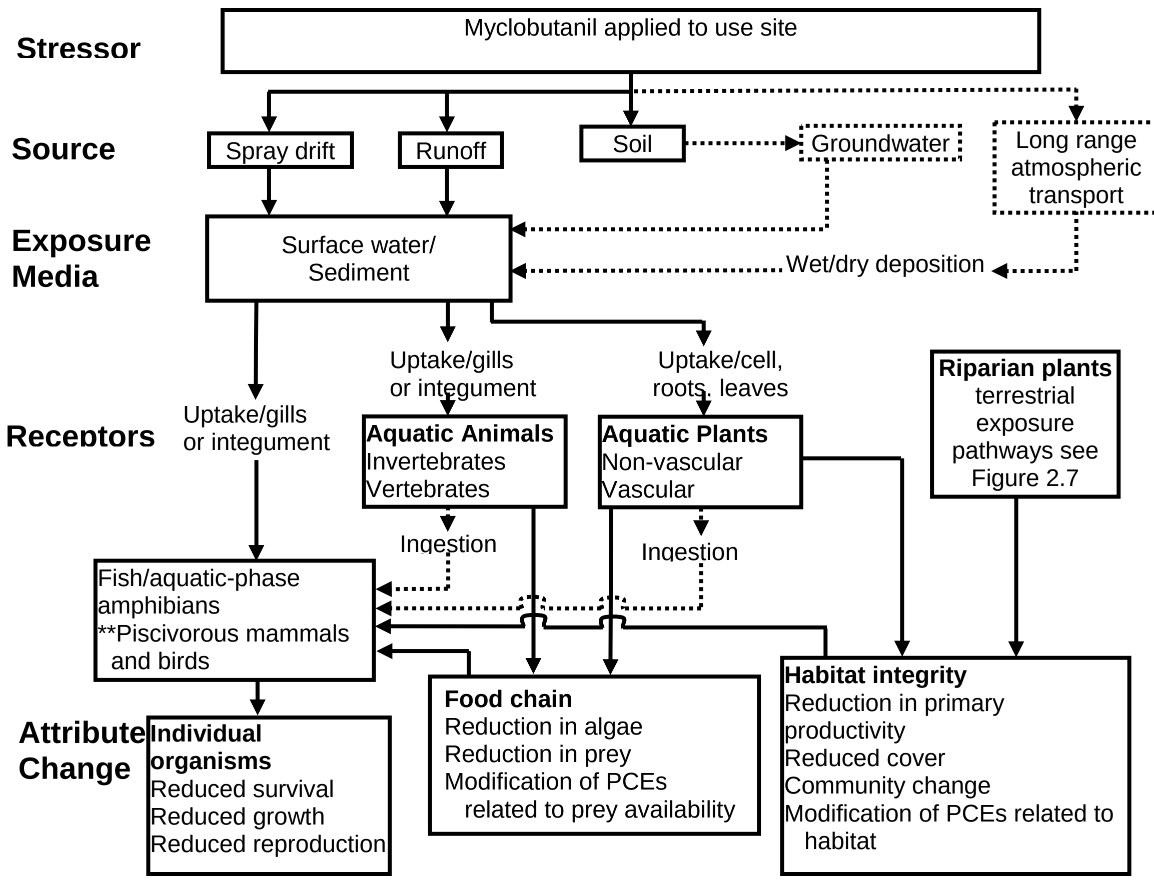


Figure 2.7 Conceptual Model for Myclobutanil Effects on Terrestrial Phase of the CRLF



** Route of exposure includes only ingestion of aquatic fish and invertebrates

Figure 2.8 Conceptual Model for Myclobutanil Effects on Aquatic Phase of the CRLF

2.10 Analysis Plan

In order to address the risk hypothesis, the potential for direct and indirect effects to the CRLF, its prey, and its habitat is estimated. In the following sections, the use, environmental fate, and ecological effects of myclobutanil are characterized and integrated to assess the risks. This is accomplished using a risk quotient (ratio of exposure concentration to effects concentration) approach. Although risk is often defined as the likelihood and magnitude of adverse ecological effects, the risk quotient-based approach does not provide a quantitative estimate of likelihood and/or magnitude of an adverse effect. However, as outlined in the Overview Document (U.S. EPA, 2004), the likelihood of effects to individual organisms from particular uses of myclobutanil is estimated using the probit dose-response slope and either the level of concern (discussed below) or actual calculated risk quotient value.

2.10.1 Measures to Evaluate the Risk Hypothesis and Conceptual Model

2.10.1.1 Measures of Exposure

The environmental fate properties of myclobutanil and the degradation product 1,2,4-triazole along with available monitoring data indicate that for myclobutanil runoff and spray drift are the principle potential transport mechanisms and for 1,2,4-triazole runoff and erosion are the principle potential transport mechanisms to the aquatic and terrestrial habitats of the CRLF. Monitoring data have also detected myclobutanil in rain water, thus secondary deposition is also a potential route of exposure but is expected to be minor. In this assessment, transport of myclobutanil and myclobutanil plus 1,2,4-triazole through runoff and spray drift is considered in deriving quantitative estimates of myclobutanil exposure to CRLF, its prey and its habitats.

Measures of exposure are based on aquatic and terrestrial models that predict estimated environmental concentrations (EECs) of myclobutanil using maximum labeled application rates and methods of application. The models used to predict aquatic EECs are the Pesticide Root Zone Model coupled with the Exposure Analysis Model System (PRZM/EXAMS). The model used to predict terrestrial EECs on food items is T-REX. The model used to derive EECs relevant to terrestrial and wetland plants is TerrPlant. These models are parameterized using relevant reviewed registrant-submitted environmental fate data.

PRZM (v3.12.2, May 2005) and EXAMS (v2.98.4.6, April 2005) are screening simulation models coupled with the input shell pe5.pl (Aug 2007) to generate daily exposures and 1-in-10 year EECs of myclobutanil and myclobutanil plus 1,2,4-triazole that may occur in surface water bodies adjacent to application sites receiving myclobutanil through runoff and spray drift. PRZM simulates pesticide application, movement and transformation on an agricultural field and the resultant pesticide loadings to a receiving water body via runoff, erosion and spray drift. EXAMS simulates the fate of the pesticide and resulting concentrations in the water body. The standard scenario used for ecological pesticide assessments assumes application to a 10-hectare agricultural field that drains into an adjacent 1-hectare water body, 2-meters deep (20,000 m^3 volume) with no outlet. PRZM/EXAMS was used to estimate screening-level exposure of aquatic organisms to myclobutanil and myclobutanil plus 1,2,4-triazole. The measure of exposure for aquatic species is the 1-in-10 year return peak or rolling mean concentration. The 1-in-10 year peak is used for estimating acute exposures of direct effects to the CRLF, as well as indirect effects to the CRLF through effects to potential prey items, including: algae, aquatic invertebrates, fish and frogs. The 1-in-10-year 60-day mean is used for assessing chronic exposure to the CRLF and fish and frogs serving as prey items; the 1-in-10-year 21-day mean is used for assessing chronic exposure for aquatic invertebrates, which are also potential prey items.

Exposure estimates for the terrestrial-phase CRLF and terrestrial invertebrates and mammals (serving as potential prey) assumed to be in the target area or in an area exposed to spray drift are derived using the T-REX model (version 1.4.1, 10/09/2008).

This model incorporates the Kenega nomograph, as modified by Fletcher et al. (1994), which is based on a large set of actual field residue data. The upper limit values from the nomograph represented the 95th percentile of residue values from actual field measurements (Hoerger and Kenega, 1972). For modeling purposes, direct exposures of the CRLF to myclobutanil through contaminated food are estimated using the EECs for the small bird (20 g) which consumes small insects. Dietary-based and dose-based exposures of potential prey (small mammals) are assessed using the small mammal (15 g) which consumes short grass. The small bird (20g) consuming small insects and the small mammal (15g) consuming short grass are used because these categories represent the largest RQs of the size and dietary categories in T-REX that are appropriate surrogates for the CRLF and one of its prey items. Estimated exposures of terrestrial insects to myclobutanil are bound by using the dietary based EECs for small insects and large insects. For granular applications, an LD_{50} per square foot is estimated based on application rate and toxicity.

Birds are currently used as surrogates for terrestrial-phase CRLF. However, amphibians are poikilotherms (body temperature varies with environmental temperature) while birds are homeotherms (temperature is regulated, constant, and largely independent of environmental temperatures). Therefore, amphibians tend to have much lower metabolic rates and lower caloric intake requirements than birds or mammals. As a consequence, birds are likely to consume more food than amphibians on a daily dietary intake basis, assuming similar caloric content of the food items. Therefore, the use of avian food intake allometric equation as a surrogate to amphibians is likely to result in an over-estimation of exposure and risk for reptiles and terrestrial-phase amphibians. Therefore, T-REX (version 1.4.1) has been refined to the T-HERPS model (v. 1.0), which allows for an estimation of food intake for poikilotherms using the same basic procedure as T-REX to estimate avian food intake.

EECs for terrestrial plants inhabiting dry and wetland areas are derived using TerrPlant (version 1.2.2, 12/26/2006). This model uses estimates of pesticides in runoff and in spray drift to calculate EECs. EECs are based upon solubility, application rate and minimum incorporation depth.

The spray drift model, AgDRIFT is used to assess exposures of terrestrial phase CRLF and its prey to myclobutanil deposited on terrestrial habitats by spray drift. In addition to the buffered area from the spray drift analysis, the downstream extent of myclobutanil that exceeds the LOC for the effects determination is also considered.

2.10.1.2 Measures of Effect

Data identified in Section 2.8 are used as measures of effect for direct and indirect effects to the CRLF. Data were obtained from registrant submitted studies or from literature studies identified by ECOTOX. The ECOTOXicology database (ECOTOX) was searched in order to provide more ecological effects data and in an attempt to bridge existing data gaps. ECOTOX is a source for locating single chemical toxicity data for aquatic life, terrestrial plants, and wildlife. ECOTOX was created and is maintained by the USEPA, Office of Research and Development, and the National Health and Environmental Effects Research Laboratory's Mid-Continent Ecology Division.

The assessment of risk for direct effects to the terrestrial-phase CRLF makes the assumption that toxicity of myclobutanil to birds is similar to or less than the toxicity to the terrestrial-phase CRLF. The same assumption is made for fish and aquatic-phase CRLF. Algae, aquatic invertebrates, fish, and amphibians represent potential prey of the CRLF in the aquatic habitat. Terrestrial invertebrates, small mammals, and terrestrial-phase amphibians represent potential prey of the CRLF in the terrestrial habitat. Aquatic, semi-aquatic, and terrestrial plants represent habitat of CRLF.

The ecotoxicity database for myclobutanil is not complete. Acceptable data are not available, either submitted or in the open literature for chronic toxicity to aquatic freshwater invertebrates, aquatic vascular plants and terrestrial plants. For the purpose of risk description in this assessment, toxicity data from other triazole sterol 14α-demethylase-inhibitors (DMIs) for these particular studies were utilized.

The acute measures of effect used for animals in this screening level assessment are the LD_{50}, LC_{50} and EC_{50}. LD stands for "Lethal Dose", and LD_{50} is the amount of a material, given all at once, that is estimated to cause the death of 50% of the test organisms. LC stands for “Lethal Concentration” and LC_{50} is the concentration of a chemical that is estimated to kill 50% of the test organisms. EC stands for “Effective Concentration” and the EC_{50} is the concentration of a chemical that is estimated to produce a specific effect in 50% of the test organisms. Endpoints for chronic measures of exposure for listed and non-listed animals are the NOAEL/NOAEC and NOEC. NOAEL stands for “No Observed-Adverse-Effect-Level” and refers to the highest tested dose of a substance that has been reported to have no harmful (adverse) effects on test organisms. The NOAEC (*i.e.*, “No-Observed-Adverse-Effect-Concentration”) is the highest test concentration at which none of the observed effects were statistically different from the control. The NOEC is the No-Observed-Effects-Concentration. For non-listed plants, only acute exposures are assessed (*i.e.*, EC_{25} for terrestrial plants and EC_{50} for aquatic plants).

It is important to note that the measures of effect for direct and indirect effects to the CRLF and its designated critical habitat are associated with impacts to survival, growth, and fecundity, and do not include the full suite of sublethal effects used to define the action area. According the Overview Document (USEPA 2004), the Agency relies on effects endpoints that are either direct measures of impairment of survival, growth, or fecundity or endpoints for which there is a scientifically robust, peer reviewed relationship that can quantify the impact of the measured effect endpoint on the assessment endpoints of survival, growth, and fecundity.

2.10.1.3 Integration of Exposure and Effects

Risk characterization is the integration of exposure and ecological effects characterization to determine the potential ecological risk from agricultural and non-agricultural uses of myclobutanil, and the likelihood of direct and indirect effects to CRLF in aquatic and terrestrial habitats. The exposure and toxicity effects data are integrated in order to evaluate the risks of adverse ecological effects on non-target species. For the assessment of myclobutanil risks, the risk quotient (RQ) method is used to compare exposure and measured toxicity values. EECs are divided by acute and chronic toxicity values. The resulting RQs are then compared to the Agency's levels of concern (LOCs) (USEPA, 2004) (see Appendix F).

For this endangered species assessment, listed species LOCs are used for comparing RQ values for acute and chronic exposures of myclobutanil directly to the CRLF. If estimated exposures directly to the CRLF of myclobutanil resulting from a particular use are sufficient to exceed the listed species LOC, then the effects determination for that use is "may affect". When considering indirect effects to the CRLF due to effects to animal prey (aquatic and terrestrial invertebrates, fish, frogs, and mice), the listed species LOCs are also used. If estimated exposures to CRLF prey of myclobutanil resulting from a particular use are sufficient to exceed the listed species LOC, then the effects determination for that use is a "may affect." If the RQ being considered also exceeds the non-listed species acute risk LOC, then the effects determination is a LAA. If the acute RQ is between the listed species LOC and the non-listed acute risk species LOC, then further lines of evidence (*i.e*. probability of individual effects, species sensitivity distributions) are considered in distinguishing between a determination of NLAA and a LAA. When considering indirect effects to the CRLF due to effects to algae as dietary items or plants as habitat, the non-listed species LOC for plants is used because the CRLF does not have an obligate relationship with any particular aquatic and/or terrestrial plant. If the RQ being considered for a particular use exceeds the non-listed species LOC for plants, the effects determination is "may affect". Further information on LOCs is provided in Appendix F.

2.10.1.4 Data Gaps

Fate

Data characterizing the environmental fate of myclobutanil and its degradation products is limited. The data was inadequate to determine the rate of formation and decline of the 1,2,4-triazole degradation product. Models currently used by EFED assume that the degradation follow first order kinetics, and therefore require an estimate of the half-life. Myclobutanil degradation, however, is best described using a hockey stick degradation pattern. This type of degradation pattern cannot be modeled using first-order kinetics.

The previously reported half-lives for myclobutanil range between 61 and 71 days, which described the decline reasonably well for the first 90 days of the study, but grossly overestimates the remaining decline. The method used to estimate these half-lives was not stated, but it appears that only the first 90 (or less) days of a 367 day study were used. EFED re-evaluated the data and re-estimated the decline rate constants utilizing all the data for myclobutanil (see discussion in Appendix C, Tables 2 and 3).

The linear regression of the log-normal transformed myclobutanil radioactivity provided the best estimate of the measured residues (as percent of applied radioactivity) versus time (e.g., 29 to 33% myclobutanil) remaining at 367 days. The study was not conducted long enough to observe a DT_{75} or DT_{90}. The 90-percent upper bound of the mean (n=2) aerobic soil metabolism half-life for myclobutanil was estimated to be 251 days.

Analysis of the Freundlich K_{ads} indicates sorption is not significantly correlated with organic matter (carbon). Therefore, lowest non-sand Freundlich K_{ads} was used to estimate the EDWCs for myclobutanil (USEPA, 2002).

Because there are no aerobic aquatic metabolism data, half-life was assumed to be twice that of the aerobic soil metabolism half-life estimated as a model input (USEPA, 2002). The anaerobic metabolism was assumed to be stable.

Ecotoxicity

No toxicity data are available for freshwater invertebrates (chronic exposure), aquatic vascular plants, and terrestrial plants. Qualitative assessments were conducted with data from similar DMI triazole fungicides, information from the open literature, and incident data.

3 Exposure Assessment

Myclobutanil is formulated as a dust, emulsifiable concentrate, granular, liquid, water dispersible granules (dry flowable), pressurized liquid, ready to use liquid, and wettable powder. Application equipment includes ground application, aerial application, chemigation, high and low volume spray, hand held, pressurized and pump up sprayers, moveable and solid set irrigation, and broadcast spreaders for granular applications. Risks from ground boom and aerial applications are expected to result in the highest off-target levels of myclobutanil due to generally higher spray drift levels. Ground boom and aerial modes of application tend to use lower volumes of application applied in finer sprays than applications coincident with sprayers and spreaders and thus have a higher potential for off-target movement via spray drift.

3.1 Label Application Rates and Intervals

Myclobutanil labels may be categorized into two types: labels for manufacturing uses (including technical grade myclobutanil and its formulated products) and end-use products. While technical products, which contain myclobutanil of high purity, are not used directly in the environment, they are used to make formulated products, which can be applied in specific areas to control brown patch, black spot, rust, powdery mildew, blights, scab, mold, and leaf spot. The formulated product labels legally limit myclobutanil's potential use to only those sites that are specified on the labels.

Currently registered agricultural and non-agricultural uses of myclobutanil within California included in this assessment are shown in Table 2.2.

3.2 Aquatic Exposure Assessment

3.2.1 Modeling Approach

Aquatic exposures are quantitatively estimated for all of assessed uses using scenarios that represent high exposure sites for myclobutanil use. Each of these sites represents a 10 hectare field that drains into a 1-hectare pond that is 2 meters deep and has no outlet. Exposure estimates generated using the standard pond are intended to represent a wide variety of vulnerable water bodies that occur at the top of watersheds including prairie pot holes, playa lakes, wetlands, vernal pools, man-made and natural ponds, and intermittent and first-order streams. As a group, there are factors that make these water bodies more or less vulnerable than the standard surrogate pond. Static water bodies that have larger ratios of drainage area to water body volume would be expected to have higher peak EECs than the standard pond. These water bodies will be either shallower or have large drainage areas (or both). Shallow water bodies tend to have limited additional storage capacity, and thus, tend to overflow and carry pesticide in the discharge whereas the standard pond has no discharge. As watershed size increases beyond 10 hectares, at some point, it becomes unlikely that the entire watershed is planted to a single crop, which is all treated with the pesticide. Headwater streams can also have peak concentrations higher than the standard pond, but they tend to persist for only short periods of time and are then carried downstream.

Crop-specific management practices for all of the assessed uses of myclobutanil were used for modeling, including application rates, number of applications per year, application intervals, and the first application date for each crop. The date of first application was developed based on several sources of information including data provided by BEAD, a summary of individual applications from the CDPR PUR data, and Crop Profiles maintained by the USDA. For example, the first applications of myclobutanil reported in the CDPR PUR database occurred in late February or early March and continued through mid-August, during the years 2001 to 2005. For grapes, the heaviest period of application began in April. Precipitation also tends to be greater in late winter and early spring then in the summer. Based upon the dates selected for crop emergence and harvest in the standard PRZM CA Grape scenario and the CDPR PUR data, the date selected for first application of myclobutanil for modeling was April 1 in (Figure 3.1).
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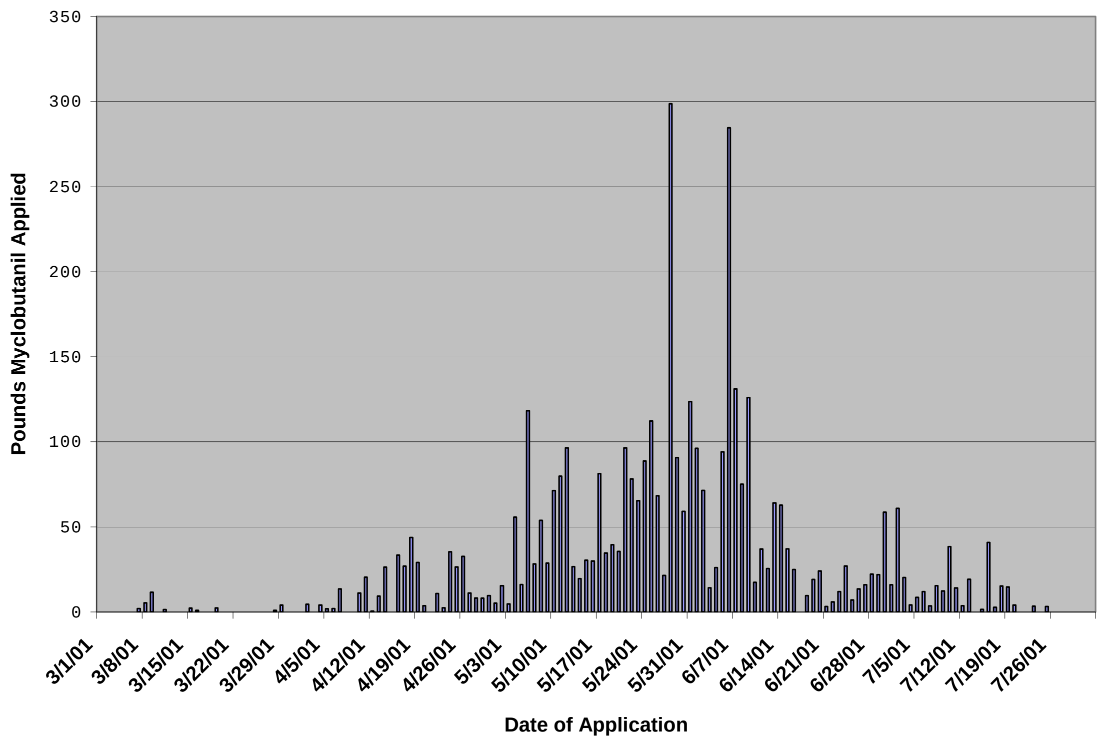

Figure 3.1 Summary of Applications (pounds versus date) of Myclobutanil to Grapes in 2001 from CDPR PUR Data.

More detail on the crop profiles and the previous assessments may be found at: http://pestdata.ncsu.edu/cropprofiles/cropprofiles.cfm

3.2.2 PRZM Scenarios

PRZM scenarios used to model aquatic exposures resulting from applications of specific uses are identified in Tables 3.5 and 3.6. In cases where a scenario does not exist for a specific use, it is necessary to assign a surrogate scenario. Those surrogates are assigned to be most representative of the use being considered. Factors considered in the selection of scenarios include the similarity of crop growth and morphology, soils, product use and cropping area. Particular attention is given to the areas where the crops are grown because rainfall is understood to be a driving variable in PRZM modeling. Justifications for assignments of surrogates are defined below. All scenarios were parameterized for irrigation.

Almond scenario (CA Almond STD)

This scenario is intended to represent almond and walnut production in CA and is therefore, directly relevant to this use. The only crop using this scenario in this assessment was almonds.

Citrus scenario (CA Citrus STD)

This scenario is intended to represent applications of pesticides to oranges, grapefruit, kumquats, lemons, limes, tangelos, and tangerines in CA and is therefore, directly relevant to this use. The crops modeled with this scenario were mangoes, papaya, sapodilla, and white sapote.

Cotton scenario (CA Cotton STD)

This scenario is intended to represent applications of pesticides to cotton in CA and is therefore, directly relevant to this use. This scenario was used for cotton seed.

Forestry Scenario (CA Forestry)

This scenario is intended to represent forestlands in northern California. The area of interest (AOI) includes Trinity, Shasta, Modoc, and Humboldt counties since they are predominantly forested and comprise the largest amount of pesticide application to forest lands in California. Based on typical forest composition and common pest species, this scenario is intended to represent coniferous evergreen forests. This scenario was used to represent Douglas Fir (seed orchard, forest, and shelter belt), loblolly pine forests, and hybrid cottonwood and poplar plantations, slash pine (forest), and ornamental and/or shade trees.

Fruit scenario (CA Fruit STD)

The CA fruit scenario represents an orchard in Fresno County, which is located in the Central Valley. This scenario is intended to represent non-citrus fruit, including apples, crabapples, pears, quince, apricots, sweet and sour cherries, nectarines, peaches, plums, and prunes. Crops modeled using this scenario were apples, apricot, canistel, cherry, mamey (mamme apple), and mayhaw (hawthorn), nectarines, peaches, plums, and prunes.

Grape Scenario (CA Grapes with Irrigation STD)

The CA grape scenario represents a vineyard located in Southern San Joaquin Valley. According to the 1997 Census of Agriculture, California is the major producer of table, wine, and raisin grapes with 85 percent of California's production in the San Joaquin Valley and the bulk of the remainder in the Coachella Valley. This scenario was used to model grapes.

Wine grapes scenario (CA Wine Grapes)

This scenario is intended to represent applications of pesticides to grapes used for wine production in CA and is therefore, directly relevant to this use. Crops considered with this scenario included blackberry, boysenberry, currant, dewberry, gooseberry, raspberry, and youngberry.

Hops Scenario (OR Hop STD)

This scenario, developed based on a hops vineyard in the Pacific Northwest, represents a vineyard located north of the area where hops are grown in CA   Since the locations where hops are grown in CA are mostly in the northern part of the state, this scenario was deemed appropriate for modeling hops grown in CA. This scenario was used to represent hops.

Lettuce Scenario (CA Lettuce STD)

A major leaf lettuce production area is the Coastal Valley of California. Since lettuce (*Lectuca sativa*) is predominantly grown on the West Coast, this scenario is used to represent lettuce production nationally. It is thus also suitable for representing lettuce culture in California and would be expected to be more vulnerable than most places in the state that grow lettuce and could impact the habitat of the red-legged frog. This scenario was used for both head and leaf lettuce.

Melon scenario (CA Melon)

This scenario is intended to represent applications of pesticides to cantaloupes, cucumbers, melons, pumpkins, watermelons, winter and summer squash in CA and is therefore, directly relevant to this use. This scenario was used to represent cantaloupes, casaba, cucumber, cucurbit vegetables, melons, squash, and watermelons.

Mint Scenario (OR Mint STD)

According to NASS data, mint (grown for oil) has been grown in Lassen, Shasta and Siskiyou Counties. These counties are located in northern CA, bordering OR. Although this scenario represents a field located north of the area where mint is grown in CA, it was developed based on a mint field in the Pacific Northwest. Since the locations where mint is grown in CA are in the northern part of the state, this scenario was deemed appropriate for modeling mint grown in CA. This scenario was used to represent spearmint and peppermint crops.

Nursery scenario (CA Nursery STD)

This scenario is intended to represent applications of pesticides in outdoor nurseries in CA and is therefore, directly relevant to this use. Uses considered with this scenario included garland, chrysanthemum, ornamental ground cover, ornamental herbaceous plants, ornamental and non-flowering plants, ornamental woody shrubs and vines.

Row crop scenario (CA Row Crop)

This scenario is intended to represent production of carrots, beans, peppers and other crops in CA, and is therefore, directly relevant to these uses. Crops considered with this scenario included artichokes, asparagus, beans, carrots, pepper, and pimento.

Strawberry scenario (CA Strawberry no plastic)

This scenario is intended to represent applications of pesticides to strawberries, non-tarped, in CA. While the majority of strawberry growers use tarps, this scenario is considered a conservative approach and is therefore, is used for strawberries.

Sugar beet scenario (CA Sugar beet OP)

This scenario was intend to represent applications of pesticides to sugar beets in CA, and is therefore, relevant to this use. This scenario was used to represent sugar beets.

Tomato scenario (CA Tomato STD)

This scenario is intended to represent applications of pesticides to tomatoes in CA and is therefore, directly relevant to this use. This scenario was used to represent eggplant, okra, and tomato crops.

Turf scenario (CA Turf)

This scenario is intended to represent applications of pesticides to sod farms, parks, recreational fields, grass for seed, and golf courses in CA and is therefore, directly relevant to this use. This scenario was used to represent Bluegrass, commercial and industrial lawns, golf-course turf, grasses grown for seed, ornamental lawns, residential lawns, sod farms, and turf.

3.2.3 Model Inputs

Myclobutanil is a fungicide used on a wide variety of food and non-food crops. Myclobutanil and selected myclobutanil plus 1,2,4-triazole environmental fate data used for generating model parameters is listed in Table 2.1. The input parameters used for PRZM and EXAMS models to estimate myclobutanil and myclobutanil plus 1,2,4-triazole are summarized in Table 3.1. Residues in surface water were estimated for myclobutanil (parent) and for myclobutanil plus 1,2,4-triazole. The number of applications and the reapplication intervals for each crop modeled are listed in Tables 3.5 and 3.6 and Appendix B (Tables 2 and 3).

Table 3.1 Summary of PRZM and EXAMS Environmental Fate Data Used for Aquatic Exposure Inputs for Myclobutanil and Myclobutanil plus 1,2,4-triazole for Endangered Species Assessment for the CRLF [1]

Parameter	Input Value and Unit	Rational
Molecular Weight	288.8 g/ mol[a,b]	
Solubility	142 ppm @ 25 ºC[a,b]	
Aquatic Photolysis ($t_{1/2}$)	0 days (Stable)	No Data
Soil Partition Coefficient, Freundlich K_{ads}	Myclobutanil: 2.39 mg/L[a] 1,2,4-triazole: 0.719 mg/L[b]	Lowest non-sand value Lowest non-sand value
Solubility in water (pH 7, 25°C)	1420 mg/L (142 mg/L * 10)[a,b]	EFED, Guidance USEPA, 2002
Vapor Pressure	1.49×10^{-06} mm Hg at 25 ºC[a]	
Henry's Law Constant	3.25×10^{-09} atm m^3/mole @ 25 ºC	
Hydrolysis	0 days (Stable)	
Aerobic Soil Metabolism ($t_{1/2}$)	Myclobutanil: 251 days[a] Myclobutanil + 1,2,4-triazol: 315 days[b]	Upper 90th bound on mean 0nly 1 value
Aerobic Aquatic Metabolism ($t_{1/2}$)	Myclobutanil *Estimated as* 502 days[a] Myclobutanil + 1,2,4-triazole *Estimated as* 630 days[b]	2 x ASM 2 x ASM per USEPA, 2002
Application Efficiency (APPEFF)	0.95 aerial spray 0.99 ground spray 1.00 granular	EFED Guidance USEPA, 2002
Drift (DRFT) Aerial Spray	Aerial (0.05 Drift) Ground (0.01Drift) Granular (0.00)	EFED Guidance USEPA, 2002
Chemical Application Method (CAM)	2 - foliar 1 – granular 5 – cotton seed (incorporation depth 3 cm)	Label

[1] – Inputs determined in accordance with EFED "Guidance for Chemistry and Management Practice Input Parameters for Use in Modeling the Environmental Fate and Transport of Pesticides" dated February 28, 2002

[a] – Value used to estimate myclobutanil EECs.

[b] – Value used to estimate myclobutanil plus 1,2,4-triazole EECs

The myclobutanil plus 1,2,4-triazole EECs were estimated by using the half-life estimated from the decline of the sum of myclobutanil and 1,2,4-triazole with time using assuming first-order kinetics (Appendix C. Environmental Fate Data) and assuming the greater mobility (Freundlich K_{ads}) of the 1,2,4-triazole (Table 3.1).

The myclobutanil was assumed to be applied by ground and aerial spray methods as a foliar, and broadcast as a granular. The other methods of application include chemigation, sprinkler irrigation, and hand sprayers. The application rates were obtained from the labels. The maximum number of applications, the maximum single application rate, and maximum total application rate per crop cycle or year, and minimum reapplication interval were used when possible. When the number of applications times the maximum single rate exceeded the labels total maximum rate per crop cycle (cc) or yearly rate, the last application was reduced so as not to exceed the total amount. Several uses (i.e., nectarines) did not have enough applications (0.15 lb ai/A/application x 7 applications = 1.05 lb ai/A/cc with a maximum per cc of 1.305 lb ai/A) to obtain the total maximum crop cycle or year rate. Eight applications at 0.15 lb ai/A/application + 1 application of 0.105 lb ai/A would be required.

3.2.4 Available Monitoring Data

3.2.4.1 Aquatic Exposure Monitoring and Field Data

Monitoring studies which included myclobutanil as an analyte were the USGS NAWQA (USGS, 1991) and the Reservoir Pilot Monitoring Program (USGS, 2001). Myclobutanil is not included in the CDPR monitoring program. These monitoring studies, which are discussed in further detail below, were not specifically targeted to myclobutanil use areas. The 1,2,4-triazole degradate was not included in the analysis.

Reservoir Pilot Monitoring Program (USGS, 2001)

Myclobutanil was included in a study that monitored a number of water supply reservoirs and finished water (USGS, 2001). Residues were detected at low concentrations in about 1 percent of 317 samples of raw water, with no detections in the finished water (Table 3.2). The degradation products were not included.

Table 3.2 Myclobutanil results from the summary of analysis of moderate-use pesticides and degradates in water samples from water supply intakes and finished-supply taps in Reservoir Pilot Monitoring Program. (USGS, 2001)

	No. of Samples	No. of Detections (Quantifiable No. of Detections)	Frequency of Detection (%)	Maximum Detection (µg/L)	Method Reporting Level (µg/L)
Raw Water	317	3 (2)	0.9	0.015	0.008
Finished Water	221	0	0	0	0.008

USGS NAWQA (National Water Quality Assessment Program)

The USGS NAWQA data was downed load on 05/13/09 (http://infotrek.er.usgs.gov/traverse/f?p=NAWQA:HOME:3748645897450568) and "contained data through water year 2007".

Surface Water Analysis

Myclobutanil was detected in ambient surface water (Table 3.3) at a detection frequency of 37.8 % (166 of 439 samples) collected in five counties in California. The maximum daily myclobutanil concentration was 0.507 µg/L for a sampling site located near Montpelier California in Merced County California (USGS Sampling Station 373112120382901). The minimum reporting limit (MRL) varies from 0.0022 to 0.25 µg/L, with a median MRL of 0.008 µg/L.

Table 3.3 Distribution of Myclobutanil Concentrations (µg/L) in USGS NAWQA Surface Water Monitoring Data Monitoring Data (1998-2007)

River Basin	County	No. samples	No. Detections	Min	Max
Santa Ana	Riverside	55	2	0.0118	0.033
San Joaquin-Tulare	Merced	149	89	0.0091	0.507
	San Joaquin	87	25	0.0045	0.021
	Stanislaus	30	15	0.0082	0.380
Sacramento	Sacramento	118	35	0.0094	0.288
	Total	439	166 (37.8%)	0.0045	0.507

Ground Water Analysis

Myclobutanil was not detected in ground water in California samples collected in California (300 samples). Wells were located in Butte, Colusa, Fresno, Glenn, Madera, Merced, Placer, Sacramento, San Bernardino, San Joaquin, Stanislaus, Sutter, Tulare, and Yuba Counties. The minimum reporting limit (MRL) varies from 0.0022 to 0.033 µg/L with a median MRL of 0.008 µg/L.

<u>*Rain data*</u>

Rainfall samples were collected during the growing seasons of 2003 and 2004 at four agriculture locations across the United States (Vogel et al., 2008). One of the watersheds was located in Western California where the cropland is comprised of almonds and vineyards with some corn and dairy. Myclobutanil (Table 3.4) was detected in 74% of rain samples (n=23), between February and April corresponding to use after almond trees bud. The myclobutanil residues were not detected in the local watershed.

Table 3.4 Myclobutanil concentrations in Rain in California Agricultural Watershed (Vogel et al., 2008)

Number of samples	Percent of Detections	Median	Maximum
23	57 % > 0.01 µg/L	0.014 µg/L	0.113 µg/L
	4 % > 0.1 µg/L		

3.2.5 Modeling Results

The estimated environmental concentrations (EECs) for myclobutanil varied by scenario, crop, and by rate and date (i.e., date of first application and reapplication interval), and method of application. The dates of the first application of myclobutanil ranged from early February to earlier September. The myclobutanil peak concentrations ranged from 2.11 µg/L to 54.56 µg/L, for cotton seed treatment to the granular application to turf, respectively. The 21-day and 60-day rolling averages were 2.1 and 2.08 µg/L, for cotton seed treatment and 54.29 to 53.84 µg/L for granular turf, respectively. The selected aquatic EECs for myclobutanil for other crops and scenarios and application practice (aerial spray, granular, and seed treatment) are listed in Table 3.5. All crops simulated (ground and aerial spray) are summarized in Appendix B, Table 1.

Table 3.5 Aquatic EECs (µg/L) for Myclobutanil Uses in California

	Method	Date of First	Representative Crop	#@rate/total/Interval	EEC 1-year in 10-year		
CA Scenario	Application			Rate	Peak	21day	60 day
Almond	as	2-10	Almond	3@0.2/0.6/7	11.93	11.86	11.77
Citrus	as	8-01	Mango	8@0.25/2.0/14	21.75	21.58	21.30
Cotton	Seed trt.	4-15	Cotton	0.89[1]	2.11	2.10	2.08
Forestry	as	8-05	Douglas fir	2@0.25 + 1@0.1/0.6/14	21.76	21.61	21.46
Forestry	as	8-05	Douglas fir	4@0.15/0.6/10	21.74	21.58	21.44
Fruit	as	3-10	Apple	4@0.5/2.0/7	29.79	29.45	28.94
Fruit	as	3-10	Apple	8@0.25/2.0/7	30.13	29.81	29.49
Fruit	as	4-10	Cherry	2@0/0.47 + 1@0.11/1.31/7	21.25	21.72	20.59
Fruit	as	4-10	Cherry	8@0.15 + 1@0.11/1.31/7	21.35	21.09	20.52
Fruit	as	4-10	Fruit[2]	8@0.25/2.0/14	31.35	30.31	30.17
Fruit	as	3-10	Peach	2@0.47 + 1@0.37/1.31/7	19.45	19.24	18.85
Fruit	as	3-10	Peach	8@0.15 + 1@0.123/1.31/7	19.88	19.69	19.39
Grapes	as	4-01	Grapes	4@0.13 + 1@0.08/0.60/7	8.99	8.88	8.73
Grapes	as	4-01	Grapes	6@0.10/0.60/7	9.07	8.98	8.83
Lettuce	as	9-02	Lettuce[3]	4@0.125/0.50/14	41.02	40.58	38.61
Melons	as	6-15	Melon	4@0.12 + 1@0.10/0.60/7	16.32	15.74	15.61
Nursery	as	7-01	Ornamental	0.26/ns[4]/2.0[5]/7	45.25	44.93	44.21
Row Crop	as	2-15	Artichoke	6@0.10/0.60/7	15.92	15.79	15.55
Row Crop	as	7-15	Asparagus	6@0.125/0.76/14	22.29	22.16	21.95
Row Crop	as	2-20	Beans	4@0.125/0.50/7	13.62	13.52	13.35
Row Crop	as	9-14	Pepper, pimento	4@0.125/0.50/10	17.70	17.52	17.34
Strawberry	as	3-01	Strawberry	6@0.125/0.75/14	34.19	34.03	33.83
Turf	Granular	2-01	Turf	6@1.34/	54.56	54.29	53.84
Turf	as	2-01	Turf	4@0.19/0.75/14	20.69	20.53	20.34

	Method	Date of First	Representative Crop	#@rate/total/Interval	EEC 1-year in 10-year		
CA Scenario	Application			Rate	Peak	21day	60 day
Hops [6]	as	9-01	Hops	4@0.25/1.0/7	28.83	28.65	28.38
Hops	as	4-01	Hops	4@0.25/1.0/7	17.96	17.82	17.56

[1] Cotton rate is 0.0625 lb a.i./100 lb seed; [4200 seed/lb; 60,000 seed/acre = 14.29 lb seed/acre]
[2] Fruit – Mamey, Mayhaw, Star Apple; canistel
[3] Lettuce and Brussels Sprouts
[4] ns is not specified on label.
[5] Ornamentals – maximum rate = 0.26 lb ai/A/application; season total = 2.0 lb ai/A/year or cc. Number of applications is not specified. Maximum seasonal rate is achieved by assuming 7 applications at 0.26 lb ai/A and an 8th application at 0.18 to obtain 2.0 lb ai/A per year. Reapplication interval is 7 days.
[6] Hops STD Scenario are located in Oregon rather than California

The estimated environmental concentrations (EECs) for myclobutanil plus 1,2,4-triazole varied by scenario, crop, and by rate, date (i.e., date of first application and reapplication interval), and method of application. The dates of the first application of myclobutanil ranged from early February to earlier September. The myclobutanil peak concentrations ranged from 2.84 µg/L to 61.41 µg/L, for cotton seed treatment to the granular application to turf, respectively. The 21-day and 60-day rolling averages were 2.82 and 2.77 µg/L, for cotton seed treatment and 61.15 to 60.71 µg/L for granular turf, respectively. The selected aquatic EECs for myclobutanil for other crops and scenarios and application practice (aerial spray, granular, and seed treatment) are listed in Table 3.6. All the crops simulated (ground and aerial spray) are summarized in Appendix B. Table 2.

Table 3.6 EECs California Red legged frog – myclobutanil + 1,2,4-triazole

		Date of First Application	Represent-ative Crop	# @ rate/total # @lb ai/A/lb ai/A/days	EEC 1-year in 10-year		
CA Scenario	Method	app		Rate	peak	21day	60 day
Almond	as	2-10	Almond	3@0.2/0.6/7	14.17	14.10	13.99
Citrus	as	8-01	Mango	8@0.25/2.0/14	27.90	27.78	27.37
Forestry	as	8-05	Douglas fir	2@0.25 + 1@0.1/0.6/14	22.37	22.28	22.10
Forestry	as	8-05	Douglas fir	4@0.15/0.6/10	22.40	22.29	22.11
Fruit	as	3-10	Apple	4@0.5/2.0/7	37.75	37.36	36.64
Fruit	as	3-10	Apple	8@0.25/2.0/7	37.94	37.63	37.16
Fruit	as	4-10	Cherry	2@0/0.47 + 1@0.37/1.31/7	25.87	25.61	25.04
Fruit	as	4-10	Cherry	8@0.15 + 1@0.11/1.31/7	24.01	24.51	24.22
Fruit	as	4-10	Fruit[1]	8@0.25/2.0/14	36.33	35.18	35.03
Fruit	as	3-10	Peach	2@0.47 + 1@0.37/7	24.55	24.29	23.88
Fruit	as	3-10	Peach	8@0.15 + 1@0.123/1.31/7	24.70	24.51	24.22
Grapes	as	4-01	Grapes	4@0.13 + 1@0.08/0.60/7	11.18	11.06	10.82

		Date of First Application	Represent-ative Crop	# @ rate/total # @lb ai/A/lb ai/A/days	EEC 1-year in 10-year		
CA Scenario	Method	app		Rate	peak	21day	60 day
Grapes	as	4-01	Grape	6@0.10/0.60/7	11.11	11.02	10.85
Lettuce	as	9-02	Lettuce[2]	4@0.125/0.50/14	41.94	41.79	41.22
Melons	as	6-15	Melon	4@0.12 + 1@0.10/0.50/7	18.61	18.41	18.21
Nursery	as	7-01	Ornamental	0.26/ns[3]/2.0[4]/7	51.96	51.71	51.22
Row Crop	as	2-15	Artichoke	6@0.10/0.60/7	17.57	17.46	17.27
Row Crop	as	7-15	Asparagus	6@0.125/0.75/14	21.09	20.99	20.68
Row Crop	as	2-20	Beans	4@0.125/0.50/7	15.56	15.48	15.35
Row Crop	as	9-14	pepper, pimento	4@0.125/0.50/10	16.97	16.91	16.82
Strawberry	as	3-01	Strawberry	6@0.125/0.75/14	40.84	40.69	40.41
Strawberry	as	3-01	Berries	4@0.063/0.25/10	14.62	14.55	14.43
Turf	Granular	2-01	Turf	6@1.34/	61.41	61.15	60.71
Turf	as	2-01	Turf	4@0.19/0.75/14	24.06	23.93	23.78
Hops [5]	as	9-01	Hops	4@0.25/1.0/7	28.81	28.65	28.38
Hops	as	4-01	Hops	4@0.25/1.0/7	20.52	20.39	20.18

[1] Fruit – Mamey, Mayhaw, Star Apple; canistel
[2] Lettuce and Brussels sprouts.
[3] ns is not specified on label.
[4] Ornamentals – maximum rate = 0.26 lb ai/A/application; season total = 2.0 lb ai/A/year or cc. Number of applications is not specified. Maximum seasonal rate is achieved by assuming 7 applications at 0.26 lb ai/A and an 8th application at 0.18 to obtain 2.0 lb ai/A per year. Reapplication interval is 7 days.
[5] Hops STD and Mint STD Scenarios are located in Oregon rather than California

In a previous assessment (USEPA, 2007), it was observed that the Tier II EECs indicated year-to-year accumulation of myclobutanil in the standard pond (Figure 3.2). This accumulation is not unexpected due to the persistence of myclobutanil and myclobutanil plus 1,2,4-triazole in soil and water environments, and the lack of inflow and outflow in the standard pond that precludes decreases in concentrations of residues due to dilution.

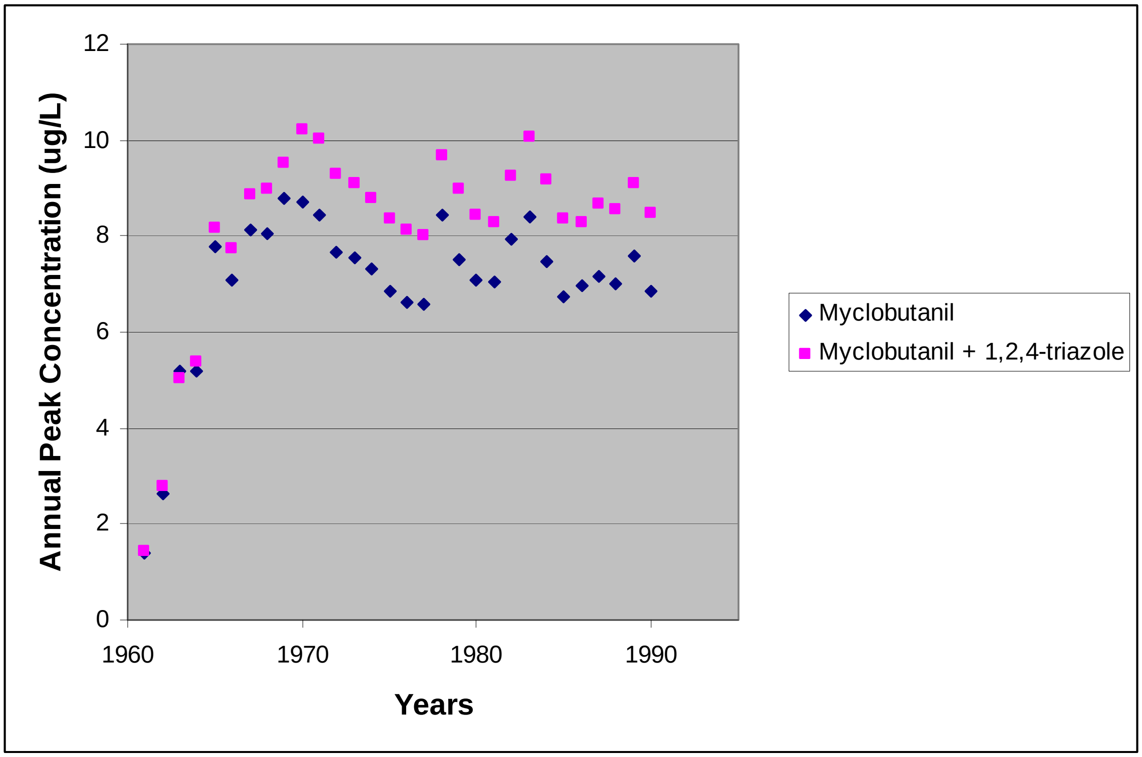

Figure 3.2 Accumulation of PRZM/EXAMS Annual Peak Concentrations of Myclobutanil and Myclobutanil plus 1,2,4-triazole in the California Tomato Scenario (surrogate for CA Okra aerial spray use)

This apparent accumulation limits any probabilistic interpretation of the return frequency of concentrations because of the accumulation over approximately 27 years simulated in the standard farm pond. Therefore, the 1-in-10 year concentrations reported in the farm pond in the standard EFED ecological risk assessments are conservative compared to flowing systems. Modeling of accumulation curves was conducted to allow for estimation of concentrations during a 30 year time period. The modeling was conducted on annual peak concentrations from PRZM/EXAMS using Sigmaplot Regression Wizard. The model used was the exponential rise to maximum model ($y = a(1-e^{(-b*x)})$) where y = annual peak concentration (µg/L), x = time (years), a= plateau concentration of accumulation, and b= annual rate of rise ($year^{-1}$). Table 3.7 shows the model parameters for several PRZM/EXAMS simulations.

Table 3.7 Time (years) for myclobutanil and myclobutanil plus 1,2,4-triazole to reach plateau concentration in standard farm pond (USEPA, 2007)

Scenario	Application Method	Model Predicted Constants		R^2
		a[1]	b[2]	
CA Okra	Air	6.1507	0.3930	0.87
	Ground	2.7613	0.4002	0.55
CA Lettuce	Air	92.26	0.24	0.76
	Ground	81.23	0.24	0.69
CA Artichoke	Air	17.40	0.23	0.94
	Ground	11.45	0.24	0.87
CA Tropical Fruit	Air	21.22	0.50	0.72
	Ground	7.66	0.76	0.15

[1] Years to reach plateau concentration in standard farm pond.
[2] Annual rate of rise ($year^{-1}$).

3.3 Terrestrial Animal Exposure Assessment

T-REX (Version 1.4.1) is used to calculate dietary and dose-based EECs of myclobutanil for the CRLF and its potential prey (e.g. small mammals and terrestrial insects) inhabiting terrestrial areas. EECs used to represent the CRLF are also used to represent exposure values for frogs serving as potential prey of CRLF adults. T-REX simulates a 1-year time period. For this assessment, spray and granular applications of myclobutanil are considered, as discussed below. In addition, the exposure estimation for use on cotton seeds assumes that the seeds are 100% available based on shallow planting conditions and an associated planting depth of ½ inch.

Terrestrial EECs for foliar formulations of myclobutanil were derived for the uses summarized in Table 3.8. Crop-specific decline data for combined residues of myclobutanil and the primary metabolite RH-9090 from submitted crop field trial studies are available for several commodities. Based on available data, foliar dissipation half-lives can be derived for pome fruit and stone fruit (19 days), caneberries (14 days), bushberries (25 days) hops (15 days), and peppers (26 days). However, no dissipation data are available for the 1,2,4-triazole and triazole conjugates (triazole alanine and triazole acetic acid) which are common degradates of myclobutanil. Using conservative assumptions that the mode of action of the parent and degradates are similar and that the compounds are of equivalent toxicity, a conservative default foliar dissipation half-life of 35 days based on the work of Willis and McDowell (1987) is used for all uses of myclobutanil. Use specific input values, including number of applications, application rate and application interval are provided in Table 3.8. An example output from T-REX is available in Appendix G.

Table 3.8 Input Parameters for Foliar Applications Used to Derive Terrestrial EECs for myclobutanil with T-REX

Use[1]	Application rate (lbs ai/A)	Number of Applications	Application Interval (days)
Almond	0.2	3	7
Apple (pressure spray/hose-end spray)	0.5	4	7
Apricot (irrigation)	0.5	2	7
Artichoke	0.125	6	14
Asparagus	0.125	6	14
Beans	0.125	4	7
Blackberry/EggPlant/Okra/Pepper/Raspberry	0.125	4	10
Boysenberry/Dewberry/Youngberry	0.0625	4	10
Carrot	0.1875	2	14
Canistel/Mango/Papaya/Sapodilla	0.25	8	14
Cherry/Nectarine/Peach (pressure spray/chemigation)	0.5	3	7
Cotton	0.06 lb ai/cwt	NS	NS
Cucurbit Vegetables	0.12	5	7
Currant	0.125	8	7
Gooseberry	0.125	8	10
Grapes	0.1	6	7
Hops	0.25	4	7
Lettuce	0.125	4	14
Plum/Prune	0.16	7	7
Tomato	0.1	4	21
Turf (ground)	1.3	4	5
Turf (granule – broadcast spreader)	1.35	6	14

[1] Aerial Application unless otherwise specified

T-REX is also used to calculate EECs for terrestrial insects exposed to myclobutanil. Dietary-based EECs calculated by T-REX for small and large insects (units of a.i./g) are used to bound an estimate of exposure to terrestrial insects. Available acute contact toxicity data for bees exposed to myclobutanil (in units of µg a.i./bee), are converted to µg a.i./g (of bee) by multiplying by 1 bee/0.128 g. The EECs are later compared to the adjusted acute contact toxicity data for bees in order to derive RQs.

For modeling purposes, exposures of the CRLF to myclobutanil through contaminated food are estimated using the EECs for the small bird (20 g) which consumes small insects. Dietary-based and dose-based exposures of potential prey are assessed using the small mammal (15 g) which consumes short grass. Upper-bound Kenega nomogram values reported by T-REX for these two organism types are used for derivation of EECs for the CRLF and its potential prey (Table 3.9). Dietary-based EECs for small and large insects reported by T-REX as well as the resulting adjusted EECs are available in Table 3.10. An example output from T-REX v. 1.3.1 is available in Appendix G.

Table 3.9 Upper-bound Kenega Nomogram EECs for Dietary- and Dose-based Exposures of the CRLF and its Prey to Myclobutanil

Use	EECs for CRLF		EECs for Prey (small mammals)	
	Dietary-based EEC (ppm)	Dose-based EEC (mg/kg-bw)	Dietary-based EEC (ppm)	Dose-based EEC (mg/kg-bw)
Almond	71	81	126	120
Apple	222	253	395	376
Apricot	126	143	225	214
Artichoke	45	51	80	77
Asparagus	56	64	100	96
Beans	55	63	99	94
Blackberry/EggPlant/Okra/Pepper/Raspberry	52	59	91	87
Boysenberry/Dewberry/Youngberry	26	29	46	44
Carrot	45	51	79	75
Canistel/Mango/Papaya/Sapodilla	124	141	221	211
Cherry/Nectarine/Peach	177	202	315	301
Cucurbit Vegetables	63	71	111	106
Currant	59	67	104	99
Gooseberry	75	85	133	127
Grapes	77	87	136	100
Hops	111	126	197	188
Lettuce	47	53	83	79
Plum/Prune	103	118	175	184
Tomato	37	32	57	55
Turf	609	693	1082	1031

Table 3.10 EECs (ppm) for Indirect Effects to the Terrestrial-Phase CRLF via Effects to Terrestrial Invertebrate Prey Items

Use	Small Insect	Large Insect
Almond	71	8
Apple	221	25
Apricot	126	14
Artichoke	45	5
Asparagus	56	6
Beans	55	6
Blackberry/EggPlant/Okra/Pepper/Raspberry	51	6
Boysenberry/Dewberry/Youngberry	26	3
Carrot	45	5
Canistel/Mango/Papaya/Sapodilla	124	14
Cherry/Nectarine/Peach	177	20
Cotton	NA	NA
Cucurbit Vegetables	63	7
Currant	59	7
Gooseberry	75	8
Grapes	77	9
Hops	111	12
Lettuce	47	5
Plum/Prune	104	12
Tomato	32	4
Turf	609	68
Turf (granular)	504	56

Myclobutanil is applied as a 0.62% ai granular formulation to non-residential and residential turf grass at a rate of 1.35 lb ai per acre. Therefore a quantitative analysis of terrestrial exposure to granular formulations was conducted. For granular applications, an LD_{50} per square foot is estimated based on application rate and toxicity.

3.4 Terrestrial Plant Exposure Assessment

TerrPlant (Version 1.1.2) is used to calculate EECs for non-target plant species inhabiting dry and semi-aquatic areas. Due to the lack of terrestrial plant data with myclobutanil, toxicity data on other conazole fungicides were used with TerrPlant and discussed in the risk description (Section 5.2.3.2). Parameter values for application rate, drift assumption and incorporation depth are based upon the use and related application method (Tables 2.2 and 3.5). As classified by Terrplant, a runoff value of 0.05 (5%) is utilized based on the solubility of myclobutanil (142 ppm). For aerial and ground application methods, drift is assumed to be 5% and 1%, respectively. EECs relevant to terrestrial plants consider pesticide concentrations in drift and in runoff. These EECs are listed by use in Table 3.11. An example output from TerrPlant v.1.2.2 is available in Appendix N.

Table 3.11 TerrPlant Inputs and Resulting EECs for Plants Inhabiting Dry and Semi-aquatic Areas Exposed to Myclobutanil via Runoff and Drift

Use	Application rate (lbs a.i./A)	Application method	Drift Value (%)	Spray drift EEC (lbs a.i./A)	Dry area EEC (lbs a.i./A)	Semi-aquatic area EEC (lbs a.i./A)
Boysenberry/Dewberry/Youngberry	0.0625	Foliar – aerial	0.05	0.003	0.006	0.034
Boysenberry/Dewberry/Youngberry	0.0625	Foliar - ground	0.01	0.0006	0.004	0.032
Grapes, tomato	0.1	Foliar – aerial	0.05	0.005	0.010	0.055
Grapes, tomato	0.1	Foliar - ground	0.01	0.001	0.006	0.051
Cucurbit Vegetables	0.12	Foliar – aerial	0.05	0.006	0.012	0.066
Cucurbit Vegetables	0.12	Foliar - ground	0.01	0.001	0.007	0.061
Artichoke, Asparagus, Beans, Blackberry/EggPlant/Okra/Pepper/ Raspberry, Currant, Gooseberry, Lettuce	0.125	Foliar – aerial	0.05	0.006	0.013	0.069
Artichoke, Asparagus, Beans, Blackberry/EggPlant/Okra/Pepper/ Raspberry, Currant, Gooseberry, Lettuce	0.125	Foliar - ground	0.01	0.001	0.008	0.064
Plum/Prune	0.16	Foliar – aerial	0.05	0.008	0.016	0.088
Plum/Prune	0.16	Foliar - ground	0.01	0.002	0.010	0.082
Carrot, Hops	0.1875	Foliar – aerial	0.05	0.009	0.019	0.103
Carrot, Hops	0.1875	Foliar - ground	0.01	0.002	0.011	0.096
Almond	0.2	Foliar - aerial	0.05	0.010	0.020	0.110
Almond	0.2	Foliar - ground	0.01	0.002	0.012	0.102
Canistel/Mango/Papaya/Sapodilla	0.25	Foliar – aerial	0.05	0.013	0.025	0.138
Canistel/Mango/Papaya/Sapodilla	0.25	Foliar - ground	0.01	0.003	0.015	0.128
Apple, Apricot, Cherry/Nectarine/Peach	0.5	Foliar - aerial	0.05	0.025	0.050	0.175
Apple, Apricot, Cherry/Nectarine/Peach	0.5	Foliar - ground	0.01	0.005	0.030	0.255
Turf	1.3	Foliar - ground	0.01	0.013	0.078	0.663
Turf	1.35	Granule broadcast spreader	0.00	0.00	0.068	0.675

4 Effects Assessment

This assessment evaluates the potential for myclobutanil to directly or indirectly affect the CRLF or affect its designated critical habitat. As discussed in Section 2.8, assessment endpoints for the CRLF effects determination include direct toxic effects on the survival, reproduction, and growth of CRLF, as well as indirect effects, such as reduction of the prey base or effects to its habitat. In addition, potential effects to critical habitat are assessed by evaluating effects to the PCEs, which are components of the critical habitat areas that provide essential life cycle needs of the CRLF. Direct effects to the aquatic-phase of the CRLF are based on toxicity information for freshwater fish, while terrestrial-phase effects are based on avian toxicity data, given that birds are generally used as a surrogate for terrestrial-phase amphibians. Because the frog's prey items and habitat requirements are dependent on the availability of freshwater fish and invertebrates, small mammals, terrestrial invertebrates, and aquatic and terrestrial plants, toxicity information for these taxa are also discussed. Acute (short-term) and chronic (long-term) toxicity information is characterized based on registrant-submitted studies and a comprehensive review of the open literature on myclobutanil.

As described in the Agency's Overview Document (U.S. EPA, 2004), the most sensitive endpoint for each taxon is used for risk estimation. For this assessment, evaluated taxa include freshwater fish (surrogate for aquatic-phase amphibians), freshwater invertebrates, aquatic plants, birds (surrogate for terrestrial-phase amphibians), mammals, and terrestrial invertebrates. No acceptable data were available for aquatic or terrestrial phase amphibians and terrestrial plants.

Toxicity endpoints are established based on data generated from guideline studies submitted by the registrant, and from open literature studies that meet the criteria for inclusion into the ECOTOX database maintained by EPA/Office of Research and Development (ORD) (U.S. EPA, 2004). Open literature data presented in this assessment were obtained from ECOTOX information obtained on October 31, 2008. In order to be included in the ECOTOX database, papers must meet the following minimum criteria:

(1) the toxic effects are related to single chemical exposure;
(2) the toxic effects are on an aquatic or terrestrial plant or animal species;
(3) there is a biological effect on live, whole organisms;
(4) a concurrent environmental chemical concentration/dose or application rate is reported; and
(5) there is an explicit duration of exposure.

Data that pass the ECOTOX screen are evaluated along with the registrant-submitted data, and may be incorporated qualitatively or quantitatively into this endangered species assessment. In general, effects data in the open literature that are more conservative than the registrant-submitted data are considered. The degree to which open literature data are quantitatively or qualitatively characterized for the effects determination is dependent on whether the information is relevant to the assessment endpoints (*i.e.*, maintenance of CRLF survival, reproduction, and growth) identified in Section 2.8. For example, endpoints such as behavior modifications are likely to be qualitatively evaluated, because quantitative relationships between modifications and reduction in species survival, reproduction, and/or growth are not available. Although the effects determination relies on endpoints that are relevant to the assessment endpoints of survival, growth, or reproduction, it is important to note that the full suite of sublethal endpoints potentially available in the effects literature (regardless of their significance to the assessment endpoints) are considered to define the action area for myclobutanil.

Citations of all open literature not considered as part of this assessment because they were either rejected by the ECOTOX screen or accepted by ECOTOX but not used (e.g., the endpoint is less sensitive) are included in Appendix H. Appendix H also includes a rationale for rejection of those studies that did not pass the ECOTOX screen and those that were not evaluated as part of this endangered species risk assessment. A detailed spreadsheet of the available ECOTOX open literature data, including the full suite of lethal and sublethal endpoints is presented in Appendix I. Appendix J contains a summary of the human health effects data for myclobutanil.

In addition to registrant-submitted and open literature toxicity information, other sources of information, including use of the acute probit dose response relationship to establish the probability of an individual effect and reviews of the Ecological Incident Information System (EIIS), are conducted to further refine the characterization of potential ecological effects associated with exposure to myclobutanil. A summary of the available aquatic and terrestrial ecotoxicity information, use of the probit dose response relationship, and the incident information for myclobutanil are provided in Sections 4.1 through 4.4, respectively.

There are three registrant-submitted studies on the toxicity of the 1,2,4-triazole degradate to aquatic organisms, but they are pending review. From these studies, it is provisionally concluded that 1,2,4-triazole has no greater toxicity to aquatic organisms than the parent compound, myclobutanil. There are currently no open literature studies reported in the ECOTOX database for 1,2,4-triazole. Each of the registrant submitted studies is briefly summarized below.

> A rainbow trout (*Salma gairdneri*) acute toxicity study (MRID 45284017) was submitted for 1,2,4-triazole. Mortality was observed only in the highest test level (1000 mg/L). The calculated LC_{50} was 760 mg/L. For myclobutanil, the rainbow trout showed a 96-hour LC_{50} of 4.2 (3.2 to 5.6, 95% C.I.) mg a.i./L (MRID 00141677). The most sensitive endpoint for myclobutanil was the bluegill sunfish 96-hour LC_{50} of 2.4 (1.5 to 4.7, 95% C.I.) mg a.i/L (MRID 00144285). Therefore, 1,2,4-triazole shows significantly less toxicity than myclobutanil.
>
> A water flea (*Daphnia magna*) acute toxicity study was submitted for 1,2,4-triazole (MRID 00133381). The calculated LC_{50} was 900 (730 to 2200, 95% C.I.) mg/L. The myclobutanil *Daphnia magna* 48-hour LC_{50} was 11 (9.5 to 13, 95% C.I.) mg a.i./L (MRID 00141678). Therefore, 1,2,4-triazole shows significantly less toxicity than myclobutanil.
>
> A non-vascular aquatic plant study for a green algae (*Scenedesmus subspicatus*) was submitted for 1,2,4-triazole (MRID 00133382). The calculated EC_{50} was 6.3 (5.5 to 7.1, 95% C.I.) mg/L. For myclobutanil, the freshwater green algae *Selenastrum capricornutum* showed a 120-hour EC_{50} of 0.83 (0.56 to 1.1, 95% C.I.) mg a.i./L based on cell density (MRID 419848-01). It is not certain which of these species is more or less sensitive, therefore it is provisionally concluded that 1,2,4-triazole shows less toxicity than myclobutanil.

Available acute and reproduction studies on the degradate 1,2,4-triazole indicate that for mammals, the degradate is either less or equally toxic as the parent. For birds, a report was submitted which indicates that 1,2,4-triazole does not have a determinate acute toxicity value with coturnix quail under the conditions of the study but is possibly less toxic than the parent, myclobutanil. This report also indicated that a single oral dose of the triazole degradate to male birds does not indicate any reproductive effects; however, the protocol of this study is not comparable to the typical avian reproduction study.

Acute mammalian toxicity data on myclobutanil formulations, including those mixed with other pesticides indicate that with one exception (the 60% formulation) the formulations are not more acutely toxic than the technical grade compound. The rat LD_{50} for the technical product is 1600 mg/kg bw, the rat LD_{50} for the 60% formulation is 980 mg/kg bw. Therefore, EEC's were derived separately for the 60% formulation using the rat LD_{50} and actual use parameters (i.e., label specified use and application rate) to determine the toxicity of the formulation relative to the technical product and/or other formulations in the field. A detailed summary of the available ecotoxicity information for 1,2,4-triazole and all myclobutanil formulated products is presented in Appendix K.

The submitted study citations can be found in Appendix O.

4.1 Evaluation of Aquatic Ecotoxicity Studies

Table 4.1 summarizes the most sensitive aquatic toxicity endpoints for the CRLF, based on an evaluation of both the submitted studies and the open literature, as previously discussed. A brief summary of submitted and open literature data considered relevant to this ecological risk assessment for the CRLF is presented below.

Table 4.1 Freshwater Aquatic Toxicity Profile for Myclobutanil

Assessment Endpoint	Species	Toxicity Value Used in Risk Assessment	MRID	Study Classification
Acute Direct Toxicity to Aquatic-Phase CRLF	Bluegill sunfish (*Lepomis macrochirus*)	LC_{50} = 2.4 mg/L	00144285	Acceptable
Chronic Direct Toxicity to Aquatic-Phase CRLF	Fathead minnow (*Pimephales promelas*)	NOAEC = 0.98 mg/L LOAEC = 2.2 mg/L	00164986 40409201 40480401	Acceptable
Indirect Toxicity to Aquatic-Phase CRLF via Acute Toxicity to Freshwater Invertebrates (i.e. prey items)	Water flea (*Daphnia magna)*	LC_{50} = 11 mg/L	00141678	Acceptable
Indirect Toxicity to Aquatic-Phase CRLF via Chronic Toxicity to Freshwater Invertebrates (i.e. prey items)	No data available for myclobutanil			

Assessment Endpoint	Species	Toxicity Value Used in Risk Assessment	MRID	Study Classification
Indirect Toxicity to Aquatic-Phase CRLF via Toxicity to Non-vascular Aquatic Plants	Freshwater green algae (*Selenastrum capricornutum*)	EC_{50} = 0.83 mg/L	419848-01	Acceptable Tier II growth and reproduction
Indirect Toxicity to Aquatic-Phase CRLF via Toxicity to Vascular Aquatic Plants	No data available for myclobutanil			

Toxicity to aquatic fish and invertebrates is categorized using the system shown in Table 4.2 (U.S. EPA, 2004). Toxicity categories for aquatic plants have not been defined.

Table 4.2 Categories of Acute Toxicity for Fish and Aquatic Invertebrates

LC_{50} (ppm)	Toxicity Category
< 0.1	Very highly toxic
> 0.1 - 1	Highly toxic
> 1 - 10	Moderately toxic
> 10 - 100	Slightly toxic
> 100	Practically nontoxic

4.1.1 Toxicity to Freshwater Fish

Given that no acceptable myclobutanil toxicity data are available for aquatic-phase amphibians, freshwater fish data were used as a surrogate to estimate direct acute and chronic risks to the CRLF. Freshwater fish toxicity data were also used to assess potential indirect effects of myclobutanil to the CRLF. Effects to freshwater fish resulting from exposure to myclobutanil may indirectly affect the CRLF via reduction in available food. As discussed in Section 2.5.3, over 50% of the prey mass of the CRLF may consist of vertebrates such as mice, frogs, and fish (Hayes and Tennant, 1985).

A summary of acute and chronic freshwater fish data is provided below in Sections 4.1.1.1 through 4.1.1.3.

4.1.1.1 Freshwater Fish: Acute Exposure (Mortality) Studies

Available data indicate that myclobutanil is moderately toxic on an acute basis to two surrogate freshwater fish species (Appendix K). The most sensitive endpoint, the bluegill sunfish 96-hour LC_{50} of 2.4 (1.5-4.7, 95% C.I.) mg a.i./L (MRID 00144285) will be used to calculate RQs for direct effects to the aquatic-phase CRLF. The probit dose-response slope used for this study is the default of 4.5 (2-9) because there were less than two concentrations at which the percent dead was between 0 and 100, thus a statistically sound calculation of the slope cannot be made from the experimental data. The acute study available for rainbow trout reported a 96-hour LC_{50} of 4.2 (3.2-5.6, 95% C.I.) mg a.i./L (MRID 00141677).

4.1.1.2 Freshwater Fish: Chronic Exposure (Early Life Stage and Reproduction) Studies

There is one submitted early life stage study for chronic freshwater fish toxicity to myclobutanil (MRID 00164986, 40409201, 40480401). Total length of juvenile fish at the end of the 35-day exposure was the most sensitive endpoint for the fathead minnow (*Pimephales promelas*); the reported NOAEC and LOAEC were 0.98 mg/L and 2.2 mg/L, respectively. At the LOAEC (2.2 mg/L) there was a 9.7% reduction in mean total length compared to the control. The LOAEC for growth as determined by wet weight was reported as 4 mg/L. The 8-day egg survival showed no significant differences between the control and any of the tested concentrations. After 35 days of exposure, 100% mortality occurred at 8.5 mg/L, the highest concentration tested.

4.1.1.3 Freshwater Fish: Sublethal Effects and Additional Open Literature Information

In the bluegill sunfish acute toxicity study (MRID 00144285) used to calculate RQs, it was reported that the test organisms exhibited quiescence and loss of equilibrium prior to death at 2.7 mg/L (LOAEC). The NOAEC for this study was 1.5 mg/L. The rainbow trout acute toxicity study (MRID 00141677) reported toxic symptoms at 3.2 mg/L (LOAEC) - the fish exhibited loss of equilibrium, surfacing, and dark coloration. Mortality was observed at 5.6 mg/L and above. The NOAEC was 1.8 mg/L

In the chronic fish early life stage study for myclobutanil (MRID 00164986, 40409201, 40480401), the raw data indicates no differences in behavior on any groups analyzed. Total length was the most sensitive endpoint. The reported NOAEC and LOAEC for total length were 0.98 mg/L and 2.2 mg/L, respectively.

There were no studies on myclobutanil toxicity to freshwater fish identified in the open literature.

4.1.1.4 Aquatic-phase Amphibian: Acute and Chronic Studies

There were no acceptable studies available for myclobutanil on toxicity to aquatic-phase amphibians.

4.1.2 Toxicity to Freshwater Invertebrates

Freshwater invertebrate toxicity data were used to assess potential indirect effects of myclobutanil to the CRLF. Effects to freshwater invertebrates resulting from exposure to myclobutanil could indirectly affect the CRLF via reduction in available food items. As discussed in Section 2.5.3, the main food source for juvenile aquatic- and terrestrial-phase CRLFs is thought to be aquatic invertebrates found along the shoreline and on the water surface, including aquatic sowbugs, larval alderflies and water striders.

A summary of acute and chronic freshwater invertebrate data is provided below in Sections 4.1.2.1 through 4.1.2.3.

4.1.2.1 Freshwater Invertebrates: Acute Exposure (Mortality) Studies

Available data indicate that myclobutanil is slightly toxic on an acute basis to *Daphnia magna*. The available study (MRID 00141678) reported the 48-hour LC_{50} for myclobutanil was 11 (9.5-13, 95% C.I.) mg a.i./L. The probit dose-response slope for this study is 6.8 (4.1-9.6, 95% C.I.).

4.1.2.2 Freshwater Invertebrates: Chronic Exposure (Reproduction) Studies

There are currently no submitted chronic freshwater invertebrate studies available for myclobutanil. It was not possible to estimate a chronic toxicity value for freshwater invertebrates using an acute to chronic ratio with estuarine/marine invertebrate data because no chronic studies are available for myclobutanil. In lieu of any myclobutanil data, toxicity data from other conazole (DMI triazole) fungicides were used to characterize risk to freshwater invertebrates, assuming that myclobutanil toxicity is similar to other conazoles due to similar mode of action. Toxicity data were obtained from the EFED database (registrant-submitted studies) for the chemicals categorized as conazole fungicides (DMI triazoles) by the Fungicide Resistance Action Committee (FRAC)[3]. Acute to chronic ratios were calculated only for conazoles with acute and chronic water flea (*Daphnia magna*) studies (the species for which acute data are available for myclobutanil). Furthermore, the only studies considered were those categorized as acceptable or supplemental, tested the technical product, and resulted in a definitive endpoint. Table 4.3 summarizes the toxicity endpoints for the nine conazole fungicides that met these data standards.

In addition to studies on the water flea (*Daphnia magna*), four of the conazoles had studies submitted for other aquatic invertebrate taxa (Fenbuconazole: MRID 46553601, Prothioconazole: MRID 46246131, Tetraconazole: MRID 46614304, and Triadimefon: MRID 00149324). For these four conazoles, *Daphnia magna* is the most sensitive aquatic invertebrate species tested.

[3] http://www.frac.info/frac/index.htm

Table 4.3 Conazole (DMI triazole) Fungicide Chronic Toxicity to Aquatic Invertebrates

Conazole[1]	48-hr EC_{50}/LC_{50} (mg/L)	MRID/ Study Classification	NOAEC (mg/L)	Most sensitive parameter	MRID/ Study Classification	ACR[2]
Cyproconazole	26	40607735/ Acceptable	0.019	Reproduction (# live offspring)	47036201/ Supplemental	1368[a]
			0.29	Reproduction (# live offspring)	43187701/ Acceptable	89.6[a]
Difenoconazole	0.77	42245110/ Acceptable	0.0056	Number of young per adult per reproductive day and adult length	42245114/ Supplemental	137.5
Fenbuconazole	2.3	41073507/ Acceptable	0.078	Reproduction and length	41875007/ Supplemental	29.5
Hexaconazole	2.9	00160502/ Acceptable	0.226	Total young and young per female reproductive day and length	42147301/ Acceptable	12.8
Prothioconazole	1.2	46246009/ Acceptable	0.51	Number of offspring per parent per reproduction day and terminal length	46246028/ Acceptable	2.4
Tebuconazole	4	40700913/ Acceptable	0.120	Adult length and survival and young per adult per reproduction day	40700915/ Acceptable	33.3
Tetraconazole	3.07	45823201/ Acceptable	0.19	Time to first brood release and reproduction (neonates/adult)	45823207/ Acceptable	13.8[b] to 16.2[c]
	2.63	44367018/ Supplemental	0.51	Survival and reproduction	44367019/ Supplemental	5.2[b] to 6.0[c]
Triadimefon	7.16	43257001/ Acceptable	0.052	Adult length	41922102/ Supplemental	137.7[d]
			0.087	Reproduction	00094679/ Supplemental	82.3[d]
Triadimenol	2.5	00126282/ Acceptable	0.199	Reproduction (# young produced)	00094680/ Acceptable	12.6

[1] Based on toxicity to *Daphnia magna*
[2] Acute-to chronic ratio
[a] Based on acute toxicity of 26 mg/L
[b] Based on acute toxicity of 2.63 mg/L
[c] Based on acute toxicity of 3.07 mg/L
[d] Based on acute toxicity of 7.16 mg/L

4.1.2.3 Freshwater Invertebrates: Sublethal Effects and Open Literature Data

In the *Daphnia magna* acute toxicity study (MRID 00141678) used to calculate RQs, it was reported that the test organisms settled to the bottom of the test vessel at 5.6 mg/L (LOAEC) and above. The NOAEC for this study was 3.2 mg/L.

There were no studies on toxicity to freshwater invertebrates identified in the open literature.

4.1.3 Toxicity to Aquatic Plants

Aquatic plant toxicity studies were used as one of the measures of effect to evaluate whether myclobutanil may affect primary production and the availability of aquatic plants as food for CRLF tadpoles. Primary productivity is essential for indirectly supporting the growth and abundance of the CRLF.

Laboratory studies were considered for determining whether myclobutanil may cause direct effects to aquatic plants. A summary of the laboratory data and freshwater field studies for aquatic plants is provided in Sections 4.1.3.1 and 4.1.3.2. There were no studies on toxicity to aquatic plants identified in the open literature.

4.1.3.1 Aquatic Plants: Laboratory Data

The available study for non-vascular aquatic plants (MRID 419848-01) examined the freshwater green algae *Selenastrum capricornutum*. This study reported a 120-hour EC_{50} for myclobutanil of 0.83 (0.56-1.1, 95% C.I.) mg a.i./L based on cell density. The NOAEC for this study was 0.56 mg/L (mean measured concentration).

There are currently no submitted studies for vascular aquatic plants available for myclobutanil. In lieu of any myclobutanil data, toxicity data from other conazole (DMI triazole) fungicides were used to characterize risk to aquatic vascular plants, assuming that myclobutanil toxicity is similar to other conazoles due to similar mode of action. Conazole toxicity data were obtained from the EFED database as described in section 4.1.2.2. Table 4.4 summarizes the toxicity endpoints for the seven conazoles with studies categorized as acceptable or supplemental that tested the technical product and resulted in a definitive endpoint.

Table 4.4 Conazole (DMI Triazole) Fungicide Toxicity to Aquatic Vascular Plants

Conazole	EC_{50} (mg/L) [1]	Most sensitive parameter	MRID	Study Classification
Bromuconazole	0.16	Frond production	42937141	Acceptable
Difenoconazole	1.9	Frond number	46950204	Supplemental
Metconazole	0.022	Frond number	46808428	Acceptable

Conazole	EC_{50} (mg/L) [1]	Most sensitive parameter	MRID	Study Classification
Propiconazole	9.02	Frond production	00133363	Supplemental
Prothioconazole	0.073	Frond number	46246101	Acceptable
Tetraconazole	0.31	Frond number	45842201	Acceptable
Triticonazole	1.4	Frond number	44802119	Acceptable

[1] Based on toxicity to duckweed (*Lemna gibba*)

4.1.3.2 Freshwater Field Studies

There are currently no submitted freshwater aquatic plant field studies available for myclobutanil.

4.2 Toxicity of Myclobutanil to Terrestrial Organisms

Table 4.5 summarizes the most sensitive terrestrial toxicity endpoints for the CRLF, based on an evaluation of both the submitted studies and the open literature. In addition to the parent myclobutanil, toxicity data on metabolites and degradates are also considered when available. RH-9090 [α-(3-hydroxybutyl)-α-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile] 6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine] (free and bound) is a major metabolite of myclobutanil in plants i.e., > 10%. RH-9090 is considered to be of equivalent toxicity to the parent based on structural activity relationship (SAR). In addition, 1,2,4-triazole and triazole conjugates (triazole alanine and triazole acetic acid) are common degradates of triazole compounds, including myclobutanil. A brief summary of submitted and open literature data considered relevant to this ecological risk assessment for the CRLF is presented below.

Table 4.5 Terrestrial Toxicity Profile for Myclobutanil

Assessment Endpoint	Species	Toxicity Value Used in Risk Assessment [1]	Citation/ MRID #	Study Classification
Acute Dose-based Direct Toxicity to Terrestrial-Phase CRLF	Bobwhite Quail (*Colinus virginianus*)	LD50 = 498 mg/kg bw	00144286	Acceptable
Acute Dietary-based Direct Toxicity to Terrestrial-Phase CRLF	Mallard Duck (*Anas platyrhynchos*)	LC50 = >4090 ppm	00144288	Acceptable
Chronic Direct Toxicity to Terrestrial-Phase CRLF	Bobwhite Quail (*Colinus virginianus*)	NOAEC = 256 ppm LOAEC >256 ppm:	43087901	Supplemental
Indirect Toxicity to Terrestrial-Phase CRLF (via acute toxicity to mammalian prey items)	Mouse	LD50 =1360 mg/kg	00165239 00141662	Acceptable
Indirect Toxicity to Terrestrial-Phase CRLF	Rat	NOAEC = 200 ppm LOAEC = 1000 ppm	00149581 00143766	Acceptable

Assessment Endpoint	Species	Toxicity Value Used in Risk Assessment [1]	Citation/ MRID #	Study Classification
(via chronic toxicity to mammalian prey items)		NOAEL = 16 mg/kg bw/day LOAEL = 80 mg/kg bw/day		
Indirect Toxicity to Terrestrial-Phase CRLF (via acute toxicity to terrestrial invertebrate prey items)	Honey bee	LD50 = > 100 µg a.i. bee (dust)	00144289	Acceptable
Indirect Toxicity to Terrestrial- and Aquatic-Phase CRLF (via toxicity to terrestrial plants)	Seedling Emergence Monocots	No Data Available		
	Seedling Emergence Dicots			
	Vegetative Vigor Monocots			
	Vegetative Vigor Dicots			

[1] All studies were conducted with the technical material (approximately 96% pure) and the toxicity values are adjusted for %a.i.

Acute toxicity to terrestrial animals is categorized using the classification system shown in Table 4.6 (U.S. EPA 2004). Toxicity categories for terrestrial plants have not been defined.

Table 4.6 Categories of Acute Toxicity for Avian and Mammalian Studies

Toxicity Category	Oral LD_{50}	Dietary LC_{50}
Very highly toxic	< 10 mg/kg	< 50 ppm
Highly toxic	10 - 50 mg/kg	50 - 500 ppm
Moderately toxic	51 - 500 mg/kg	501 - 1000 ppm
Slightly toxic	501 - 2000 mg/kg	1001 - 5000 ppm
Practically non-toxic	> 2000 mg/kg	> 5000 ppm

4.2.1 Toxicity to Birds

As specified in the Overview Document, the Agency uses birds as a surrogate for terrestrial-phase amphibians when amphibian toxicity data are not available (U.S. EPA, 2004). No terrestrial-phase amphibian data are available for myclobutanil; therefore, acute and chronic avian toxicity data are used to assess the potential direct effects of myclobutanil to terrestrial-phase CRLFs.

4.2.1.1 Birds: Acute Exposure (Mortality) Studies

Based on the submitted acute oral toxicity study for the Bobwhite Quail (MRID 00144286), myclobutanil is categorized as moderately toxic to birds on a dose basis with an acute LD_{50} of 498 (408-598, 95% C.I.) mg/kg bw.

Based on avian subacute dietary studies for two bird species, myclobutanil is categorized as slightly toxic on a dietary basis with subacute dietary LC_{50}'s of >4090 ppm for mallard duck (MRID 00144288) and > 4530 ppm for bobwhite quail (MRID 00144287). Although no definitive subacute dietary LC_{50}s could be determined from these studies, there were mortalities in both studies. There was one mortality at 4090 ppm, the highest concentration tested in the mallard duck study and mortalities at 3000 ppm and 4530 ppm, the highest concentration tested in the bobwhite quail study.

Table 4.7 Avian Acute Toxicity Data

Common Name	**%AI**	**Study parameters**	**LD_{50}/LC_{50} NOAEC/ LOAEC**	**MRID**	**Classification/ Category**
Bobwhite Quail *Colinus virginianus*	84.5	Acute oral study 10 birds/dose level 21 day observation period 0 (vehicle), 316, 464, 681, 1000, 1470 mg/kg tested	LD_{50} **498 (408 – 598) mg/kg bw**[1] Slope = 7.03 (3.5-10.5) NOAEL not determined LOAEL 316 mg/kg (lethargy and anorexia). Mortalities at all dose levels (1, 4, 8, 10 and 10, respectively). Good dose response; NOAEL not critical in this case.	00144286	Acceptable Moderately toxic
Bobwhite Quail *Colinus virginianus*	84.5	Subacute dietary study 10 birds/concentration level 5 days on treatment, 3 days observation 0 (vehicle), 246, 641, 1150, 3000, 4530 ppm tested (measured concentrations)	LC_{50} >4530 ppm NOAEC: 1150 ppm LOAEC: 3000 ppm Mortality: 2 at 3000 ppm and 1 at 4530 ppm. Anorexia and lethargy at 3000 and 4530 ppm	00144287	Acceptable Slightly toxic

Common Name	%AI	Study parameters	LD_{50}/LC_{50} NOAEC/ LOAEC	MRID	Classification/ Category
Mallard Duck *Anas platyrhynchos*	84.5	Subacute dietary study 10 birds/concentration level 5 days on treatment, 3 days observation 0 (vehicle), 270, 620, 1250, 2220, 4090 ppm tested (measured concentrations)	LC_{50} >**4090 ppm** NOAEC: 1250 ppm LOAEC: 2220 ppm (anorexia and lethargy). One bird died at 4090 ppm.	00144288	Acceptable Slightly toxic

[1] **Bold** value is the value that will be used to calculate risk quotients

4.2.1.2 Birds: Chronic Exposure (Growth, Reproduction) Studies

Two avian chronic toxicity studies are available for myclobutanil. One-generation reproductive toxicity studies were conducted on both the mallard duck and bobwhite quail (MRID numbers 43087901 and 43087902). The studies were conducted simultaneously using the same dosing regimen. In both studies, no adverse effects were seen at the maximum level tested. Therefore, the NOAEC for both studies is 256 ppm and the LOAEC is > 256 ppm. The studies are classified as supplemental since no LOAEC was established and the concentrations tested are expected to be relatively low when compared to terrestrial EECs . The NOAEC of 256 ppm is used for risk estimation.

RH-9090 [α-(3-hydroxybutyl)-α-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile] 6-chloro-3-pyridinyl)methyl]-*N*-nitro-2-imidazolidinimine] (free and bound) is a major metabolite of myclobutanil in plants i.e., > 10%. RH-9090 is considered to be of equivalent toxicity to the parent based on structural activity relationship (SAR). In addition, 1,2,4-triazole and triazole conjugates (triazole alanine and triazole acetic acid) are common degradates of triazole compounds, including myclobutanil. A submitted report is available which indicates that the acute LD_{50} of the 1,2,4-triazole degradate in coturnix quail is >316 mg triazole/kg bird (MRID 45284015). This report also contains a reproduction study in which male birds were treated to a single oral dose of 316 mg triazole/kg bird. No mortality was observed and there was no indication of reproductive effects. This report has not yet been reviewed. In addition, this protocol is not comparable to the standard submitted avian reproduction study.

Table 4.8 Avian Chronic Toxicity Data

Common Name	%AI	Study Parameters	NOAEC/LOAEC	MRID	Classification/ Category
Bobwhite Quail *Colinus virginianus*	94.2	Reproduction study Mean measured concentrations: 0 (vehicle), 72.5, 124.2, 181.8, 255.8 ppm for 22 consecutive weeks to 18 week old quail. 16 pairs per concentration level	NOAEC = **256 ppm**[1] LOAEC >256 ppm No treatment-related effects at any level. Not tested at sufficiently high concentration levels	43087901	Supplemental
Mallard Duck *Anas platyrhynchos*	94.2	Reproduction study Mean measured concentrations: 0 (vehicle), 72.5, 124.2, 181.8, 255.8 ppm for 22 consecutive weeks to 17 week old ducks. 16 pairs per concentration level	NOAEC = 256 ppm LOAEC >256 ppm No treatment-related effects at any level. Not tested at sufficiently high concentration levels	43087902	Supplemental

[1] **Bold** value is the value that will be used to calculate risk quotients

4.2.1.3 Birds: Sublethal Effects and Additional Open Literature

In the acute oral toxicity study for the bobwhite quail (MRID 00144286), it was reported that the test organisms exhibited lethargy and anorexia at all dose levels. The LOAEL for this study was 316 mg/kg (lowest dose tested). The NOAEL was not determined for sublethal effects. In the mallard duck subacute dietary study used for risk estimation (MRID 00144288), anorexia and lethargy were observed in birds at and above 2500 ppm starting at day two and ending on day 4. After day four all birds appeared normal. The NOAEC was 1250 ppm. The subacute dietary study with bobwhite quail also exhibited anorexia and lethargy at 3000 and 4530 ppm. There were no avian studies available in the ECOTOX open literature for myclobutanil.

4.2.2 Toxicity to Mammals

Mammalian toxicity data are used to assess potential indirect effects of myclobutanil to the terrestrial-phase CRLF. Effects to small mammals resulting from exposure to myclobutanil could indirectly affect the CRLF via reduction in available food. As discussed in Section 2.5.3, over 50% of the prey mass of the CRLF may consist of vertebrates such as mice, frogs, and fish (Hayes and Tennant 1985).

4.2.2.1 Mammals: Acute Exposure (Mortality) Studies

Available acute toxicity data for the TGAI and several formulations with the mouse and rat are available for myclobutanil. The available data suggest that myclobutanil is slightly toxic to small mammals on an acute oral basis (**Appendices J and K**). The most sensitive endpoint for the TGAI, the mouse LD_{50} of 1360 mg/kg, will be used to estimate risk to the CRLF via indirect effects to mammals. The probit dose-response slope for this study is 1.19 with no confidence interval provided.

Acute toxicity data with the mouse on the 1,2,4-triazole degradate indicates that it is not more acutely toxic than the parent. The acute LD_{50} is 3650 mg/kg bw (MRID 45284001).

With the exception of the 60 DF formulation, the myclobutanil formulations, including those mixed with other pesticides are not more acutely toxic to mammals than the technical material. The 60 DF formulation has a rat LD_{50} of 980 mg formulation/kg bw and may therefore be more toxic than the technical material but still falls within the category of slightly toxic. Risk estimations are conducted for the 60 DF formulation with the rat to ensure that the assessment is protective of acute mammalian exposure to the DF formulation.

Table 4.9 Mammalian Acute Toxicity Data

Common Name	**%AI**	Study parameters	**LD_{50} /NOAEL**	**MRID**	**Classification/ Category**
Laboratory mouse *Mus musculus*	91.9	Acute oral study 0, 1.3, 2.0, 3.2, 5.0 g/kg bw tested 10/dose level 14-day observation period	Acute oral LD_{50}=**1360 mg/kg bw** in female mice (most sensitive species (original DER mistakenly stated that it was in the rat)). Mortality at all dose levels tested. Multiple clinical signs, including ataxia, tremors, loss of righting and others – not dose-related; however, early deaths may have affected reporting. Probit slope: 1.19.	00165239 00141662	Acceptable Slightly toxic[1]
Laboratory mouse *Mus musculus*	1,2,4-triazole	Acute oral study	LD_{50} = 3650 mg/kg	45284001	Practically nontoxic

[1] Based on LD_{50} (mg/kg) <10 very highly toxic; 10-50 highly toxic; 51-500 moderately toxic; 501-2000 slightly toxic; >2000 practically nontoxic
[2] **Bold** value is the value that will be used to calculate risk quotients

Table 4.10 Acute Rat Toxicity Comparison of Myclobutanil Formulations

Formulation (%)	LD_{50} (mg/kg bw)	MRID
Technical Product	1600 (M) 2290 (F)	00141662
1.5% with 2.5% permethrin	> 5050 (M & F)	44155803
2.25% with 60% mancozeb	> 5000 (M)	40149003
60% formulation with inerts	980 (M) 1235 (F)	00164467, 00164468
Fludioxonil, 1.45%; Mefenoxam, 3.61%; Azoxystrobin, 8.55%; and Myclobutanil, 9.75%	5979 (F)	47092603
Up-and-Down Method: 0.9% Myclobutanil (granules)	> 5000 (F)	46886701
1% formulation	> 5000 (M & F)	45381001
21% formulation	3749 (F) >5000 (M)	45218401
6.0% formulation	LD_{50} between 500 & 5,000 (M & F)	45056903
1% formulation	> 5,000 (M & F)	44265201

4.2.2.2 Mammals: Chronic Exposure (Growth, Reproduction) Studies

In a two-generation reproduction study in rats on myclobutanil (MRIDs 00149581 and 00143766), the NOAEC/NOAEL used in the assessment is 200 ppm/16 mg/kg bw/day with a LOAEC/LOAEL of 1000 ppm/80 mg/kg bw/day based on a decrease in pup body weight gain during lactation, an increased incidence in the number of stillborns and atrophy of the testes and prostate (offspring systemic and reproductive endpoints). These endpoints were used in the risk assessment because the parental systemic toxicity endpoints are not considered to be relevant to either growth or reproductive effects (MRID 00149581).

As previously noted, RH-9090 is a major metabolite of myclobutanil. It is considered to be of equivalent toxicity to the parent based on SAR and tolerances for myclobutanil residues in food are established for the combined residues of myclobutanil and RH-9090 on registered commodities.

In addition, 1,2,4-triazole and triazole conjugates (triazole alanine and triazole acetic acid) are common degradates of triazole compounds, including myclobutanil. The 1,2,4-triazole degradate was tested in a two-generation reproduction study (MRID 46467304). The parental NOAEL/LOAEL is <15 mg/kg bw/day/15 mg/kg bw/day based on a decrease in bodyweight and bodyweight gain and decrease in spleen weight. The offspring NOAEL/LOAEL is <19 mg/kg bw/day/19 mg/kg bw/day based on decrease in bodyweight and bodyweight gain and brain and spleen weight. The reproductive NOAEL/LOAEL is 15/31 mg/kg bw/day based on abnormal sperm and a decrease in the number of corpora lutea. At 218 mg/kg bw/day, there was reproductive failure (no viable offspring) and an increase in corpora lutea in F_0 parental females. A comparison of the endpoints between the parent and the degradate, indicates that the degradate may have a greater effect on bodyweight and bodyweight gain for both parents and pups; however, the endpoint values for reproductive effects for the parent are equivalent to the degradate. There is an uncertainty due to dose spacing; however, the results indicate that the degradate is at least as toxic as the parent.

Toxicity data are also available for the degradate triazole alanine. Other triazole conjugates are considered to be toxicologically equivalent to triazole alanine.
A two-generation rat reproduction study conducted on triazole alanine (MRID 00164112) indicates that the triazole conjugates exhibit less toxicity than the parent. Maternal/parental toxicity was not seen in the rat reproduction study at the highest dose tested (929/988 M/F mg/kg bw/day). Reproductive toxicity was also not seen at the highest dose tested. The offspring NOAEL/LOAEL is 192/929 mg/kg bw/day based on reduced mean litter weights in both generations.

Since 1,2,4-triazole and triazole conjugates are common degradates of triazole compounds and the mechanism of toxicity of these compounds is considered to be fundamentally different than the toxicity for the parent triazoles (e.g., myclobutanil), separate human health risk assessments have been conducted for 1,2,4-triazole and triazole conjugates. (February 7, 2006, 1,2,4-Triazole, Triazole Alanine, Triazole Acetic Acid: Human Health Aggregate Risk Assessment in Support of Reregistration and Registration Actions for Triazole-derivative Fungicide Compounds DP322215).

4.2.2.3 Mammals: Open Literature

A review of mammalian studies available in the ECOTOX open literature for myclobutanil indicates that no additional toxicity data relevant to the myclobutanil CRLF assessment were provided in the open literature i.e., none of the available mammalian studies identified a more sensitive endpoint. Therefore, only toxicity data provided in submitted studies were used to assess mammalian effects.

Table 4.11 Mammalian Chronic Toxicity Data

Common Name	**%AI**	**Study Parameters**	**NOAEC/ LOAEC**	**MRID**	**Classification/ Category**
Laboratory rat *Rattus norvegicus*	84.5	2-Generation reproduction study 25 rats/sex/group 0, 50, 200 or 1000 ppm 4, 16 or 80 mg/kg bw/day based on overall mean concentration of active ingredient in dietary analyses.	Parental NOAEC/NOAEL: 50 ppm/4 mg/kg bw/day Parental LOAEC/LOAEL: 200 ppm/16 mg/kg bw/day based on hepatocellular hypertrophy and increases in liver weights. Offspring/Reproductive NOAEC/NOAEL: **200 ppm/16 mg/kg/day** Offspring/Reproductive LOAEC/LOAEL: 1000 ppm/80 mg/kg/day based on testicular, epididymal and prostatic atrophy in P_2 males; slight increase in stillborns, decrease in body weight gain in pups during lactation in F_1 and F_2 generations.	00149581 00143766	Acceptable

Common Name	%AI	Study Parameters	NOAEC/ LOAEC	MRID	Classification/ Category
Laboratory rat *Rattus norvegicus*	1,2,4-triazole	Reproduction and fertility effects 0, 250, 500, 3000 ppm **M:** 15, 31, 189 mkd **F:** 18, 36, 218 mkd	Parental NOAEC/NOAEL: <250 ppm/15 mg/kg/day Parental LOAEC/LOAEL: 250 ppm/15 mg/kg/day based on decrease in bodyweight, bodyweight gain and spleen weight. Offspring NOAEC/NOAEL: <250 ppm/19 mg/kg/day Offspring LOAEC/LOAEL: 250 ppm/19 mg/kg/day based on decrease in bodyweight, bodyweight gain, brain and spleen weights Repro NOAEC/NOAEL: 250 ppm/15 mg/kg/day Repro LOAEC/LOAEL: 500 ppm/31 mg/kg/day based on abnormal sperm and ↓# of CL in F_1 females At 3000 ppm/218 mg/kg/day, reproductive failure (no viable offspring), ↑CL in F_0 parental females	46467304	Acceptable
Laboratory rat *Rattus norvegicus*	Triazole Alanine	Reproduction and fertility effects 0, 200, 2000, 10000 ppm **M:** (F0/F1) 0, 50/47, 213/192, 1098/929 mg/kg/day **F:** 0, 51/49, 223/199, 1109/988 mg/kg/day	Parental NOAEC/NOAEL: 10000 ppm/929 mg/kg/day Parental LOAEC/LOAEL: >10000 ppm/929mg/kg/day Offspring NOAEC/NOAEL: <250 ppm/19 mg/kg/day Offspring LOAEC/LOAEL: 2000ppm/192 mg/kg/day based on reduced mean litter weights in both generations Repro LOAEC/LOAEL: >10000 ppm/929mg/kg/day	00164112	Acceptable

[1] **Bold** value is the value that will be used to calculate risk quotients

4.2.3 Toxicity to Terrestrial Invertebrates

Terrestrial invertebrate toxicity data are used to assess potential indirect effects of myclobutanil to the terrestrial-phase CRLF. Effects to terrestrial invertebrates resulting from exposure to myclobutanil could indirectly affect the CRLF via reduction in available food.

4.2.3.1 Terrestrial Invertebrates: Acute Exposure (Mortality) Studies

Myclobutanil is classified as non-toxic to bees with an acute contact LD50 of >362 µg/bee (MRID 00144289). The bees were exposed to a finished dust containing 27.58% a.i. in a bell jar vacuum duster at dosages of approximately 120, 240 or 362 µg technical material per bee. Observations for clinical signs of toxicity were made daily for at 24 hour intervals from 24 to 96 hours. Mortality in the treated bees did not differ from the untreated controls.

4.2.3.2 Terrestrial Invertebrates: Open Literature Studies

There are several terrestrial invertebrate toxicity studies available in the open literature (Appendices H and I). Five acceptable literature studies were reviewed for this assessment; one study on beneficial arthropods, three studies on predacious mites and one study on mirids, a predacious insect (EcoReference Nos.: 104765, 96453, 64063, 63621, 63599). These studies were used qualitatively as part of a weight of the evidence analysis/determination. The arthropods study showed myclobutanil to be harmless to all of the five arthropods tested including, parasitic wasps, lady-birds, hoverfly, rove beetle, and carabid beetle. The three mite studies showed no adverse effects on the four species evaluated. In the study on the mired, myclobutanil showed moderate toxicity (LD_{50} = 150 µg ai/L) to adult mirid at the manufacturer's label rate of 440 µg ai/L but no toxicity to nymphs.

Although one of the available open literature studies identified a more sensitive endpoint than the submitted honey bee toxicity study that determined a dust LD_{50} of > 100 µg/bee, the weight of the evidence indicates that myclobutanil is non-toxic to terrestrial invertebrates. Four of the five studies clearly showed that myclobutanil was not toxic to terrestrial invertebrates at label rates. Only one of the five available acceptable studies provided an LD_{50}. That study indicated moderate toxicity to adult mirids only with no toxicity to the nymphs. Myclobutanil toxicity to adults was unexpected because myclobutanil was seen to be innocuous to all stages of mites in three literature studies and mites are usually more easily intoxicated than insects (mirids). Therefore, based on the totality of the available data, the honey bee study represents the most appropriate study for endpoint selection.

4.2.4 Toxicity to Terrestrial Plants

Terrestrial plant toxicity data are used to evaluate the potential for myclobutanil to affect riparian zone and upland vegetation within the action area for the CRLF. Impacts to riparian and upland (i.e., grassland, woodland) vegetation could result in indirect effects to both aquatic- and terrestrial-phase CRLFs, as well as effects to designated critical habitat PCEs via increased sedimentation, alteration in water quality, and reduction of upland and riparian habitat that provides shelter, foraging, predator avoidance and dispersal for juvenile and adult CRLFs.

There are currently no registrant-submitted terrestrial plant toxicity data for myclobutanil with which to assess the potential for indirect effects to the aquatic- and terrestrial-phase CRLF via effects to riparian vegetation or effects to the primary constituent elements (PCEs) relevant to the aquatic- and terrestrial-phase CRLF. However, there is some evidence in the open literature that myclobutanil has the potential to elicit phytotoxic effects. Three terrestrial plant studies were reviewed for this assessment. No adverse effects were observed in two of the three studies (EcoReference Nos.: 104715, 104728, 76524). In a cucumber study, myclobutanil sprayed onto seedlings at the first true leaf (application rate not provided) did not affect fruit quality. In a seed treatment study, infected spring wheat treated with myclobutanil at a rate of 0.12 g/ ai./kg seed performed similarly to untreated seed. In the third study, myclobutanil was applied at two rates (6.1 g ai/100 m^2 (0.54 lbs/A) and 12.19 g/ai 100 m^2 (1.09 lbs/A)) to "Tifgreen" Bermuda grass to determine if it would produce a plant growth regulation effect on healthy Bermuda grass. After three applications at 28 to 30 day intervals, compared to the control, the high rate of myclobutanil significantly decreased turf grass quality on at least one evaluation date in each year of the study.

In order to characterize potential effects to terrestrial plants following exposure to myclobutanil in the risk description, terrestrial plant data from 5 other triazole DMI fungicides were obtained and used as inputs values in the TerrPlant (v. 1.2.2) model for terrestrial plants. Table 4.12 summarizes the toxicity values and endpoints for the 5 triazole fungicides.

Table 4.12 Terrestrial Plant Toxicity Data for 5 Other DMI Fungicides

Fungicide	**EC_{25} (lbs a.i./A)**		**NOAEC/EC_{05} (lbs a.i./A)**		**Effect/MRID**	
	Seedling Emergence	Vegetative Vigor	Seedling Emergence	Vegetative Vigor	Seedling Emergence	Vegetative Vigor
Metconazole						
Monocot	0.78	>0.6	0.3	0.6	Ryegrass: reduced plant height 46805103	46805104
Dicot	0.15	0.44	0.075	0.0036 (EC_{05})	Radish: reduced plant height 46805103	Radish: reduced dry weight 46805104
Prothioconazole						
Monocot	>0.272	>0.272	0.272	0.272	46246049	46246049
Dicot	>0.272	>0.272	0.03	<0.272	Cucumber: shoot height and dry	46246049

Fungicide	EC$_{25}$ (lbs a.i./A)		NOAEC/EC$_{05}$ (lbs a.i./A)		Effect/MRID	
	Seedling Emergence	Vegetative Vigor	Seedling Emergence	Vegetative Vigor	Seedling Emergence	Vegetative Vigor
					weight 46246049	
Cyproconazole						
Monocot	>0.64	>0.62	0.64	0.62	46218512	46218511
Dicot	0.091	0.50	0.066	0.09	Cabbage: fresh weight 46218512	Cabbage: dry weight 46218511
Propiconazole						
Monocot	> 1.5	0.315	1.5	0.0815	41673201	Rye grass: plant height 41673203
Dicot	0.18	0.039	0.056	0.056	Cabbage: dry weight 41673201	Cabbage: dry weight 41673203
Triticonazole						
Monocot	>4.25	>4.2	1.3	4.2	Rye grass: shoot length 44802116	44802116
Dicot	0.015	1.3	0.004	1.0	Lettuce: shoot length 44802116	Turnip: dry weight 44802116

4.3 Use of Probit Slope Response Relationship to Provide Information on the Endangered Species Levels of Concern

The Agency uses the probit dose response relationship as a tool for providing additional information on the potential for acute direct effects to individual listed species and aquatic animals that may indirectly affect the listed species of concern (U.S. EPA, 2004). As part of the risk characterization, an interpretation of acute RQ for listed species is discussed. This interpretation is presented in terms of the chance of an individual event (i.e., mortality or immobilization) should exposure at the EEC actually occur for a species with sensitivity to myclobutanil on par with the acute toxicity endpoint selected for RQ calculation. To accomplish this interpretation, the Agency uses the slope of the dose response relationship available from the toxicity study used to establish the acute toxicity measures of effect for each taxonomic group that is relevant to this assessment. The individual effects probability associated with the acute RQ is based on the mean estimate of the slope and an assumption of a probit dose response relationship. In addition to a single effects probability estimate based on the mean, upper and lower estimates of the effects probability are also provided to account for variance in the slope, if available.

Individual effect probabilities are calculated based on an Excel spreadsheet tool IECV1.1 (Individual Effect Chance Model Version 1.1) developed by the U.S. EPA, OPP, Environmental Fate and Effects Division (June 22, 2004). The model allows for such calculations by entering the mean slope estimate (and the 95% confidence bounds of that estimate) as the slope parameter for the spreadsheet. In addition, the acute RQ is entered as the desired threshold.

4.4 Incident Database Review

A review of the EIIS database for ecological incidents involving myclobutanil was completed on May 26, 2009. Three incident reports were filed for myclobutanil between 1994 and 2003, all with effects on terrestrial plants (two incidents with grapes and one with roses). The two incidents with grapes occurred in California and the one with roses was reported in Maryland. The certainty index for the damage in all 3 incidents was rated as possibly related to exposure to myclobutanil. The two incidents with grapes involved application of other pesticides as well as the myclobutanil. Therefore, it is unclear whether the effects were due to exposure to myclobutanil in these two incidents. Myclobutanil was the only pesticide applied to the rose bushes in the third reported incident. A brief description of each of the reported incidents is provided below.

It should be noted that these reported incidents may only represent a fraction of actual incidents. Actual incidents may not have been reported due to various factors such as lack of reporting, or a lack of witness to effects. Therefore, the lack of an incident report does not necessarily indicate a lack of an incident.

Complete incident tables are provided in Appendix L.

4.4.1 Terrestrial Incidents

Between 5/30/1994 and 6/3/1994, Rally 40W (myclobutanil), Pro Gibb (gibberellic acid), Dimethogan 25 WP, Pro Kil Cryolite 96 (sodium fluoaluminate), Britz binder, and Booster 42 Foliar Spray (polymeric polyhydroxy acids) were applied by ground spray to grape vines. Shortly after the last application, scarring of the berries, stunted vine growth, lack of berry size increase, dieback of fruit from total bunches, and limited cone growth with straggly branches were observed. No residue analysis was conducted. The California Commissioner's report indicated that mixtures of Pro-Gibb 4% and Pro-Kil Cryolite 96 may cause some compatibility problems. The certainty index for this incident (I002621-006) is possible.

It was reported that Rally 40W (myclobutanil) damaged 6 acres of Red Globe and Thompson's grapes to the point that they could not be sold. Burns and necrosis on bunches (Red Globe) and leaf burn (Thompson's) was observed. AGRI-MEK (abamectin) and Ad-Wet were also applied, using a ground spray on the vineyard. The certainty index for this incident (I013563-014) is possible.

Systhane (myclobutanil) was applied via a broadcast ground spray to rose bushes grown in greenhouses by local residents in Maryland. The total magnitude was 200 houses. Foliar necrosis and some defoliation were observed after exposure to Systhane. Damage varied from house to house and by rose variety. The certainty index for this incident (I014702-074) is possible.

No incidents involving terrestrial animals were reported.

4.4.2 Aquatic Incidents

No incidents involving aquatic plants or animals were reported.

5 Risk Characterization

Risk characterization is the integration of the exposure and effects characterizations. Risk characterization is used to determine the potential for direct and/or indirect effects to the CRLF or to its designated critical habitat from the use of myclobutanil in CA. The risk characterization provides an estimation (Section 5.1) and a description (Section 5.2) of the likelihood of adverse effects; articulates risk assessment assumptions, limitations, and uncertainties; and synthesizes an overall conclusion regarding the likelihood of adverse effects to the CRLF or its designated critical habitat (i.e., “no effect,” “likely to adversely affect,” or “may affect, but not likely to adversely affect”).

5.1 Risk Estimation

Risk is estimated by calculating the ratio of exposure to toxicity. This ratio is the risk quotient (RQ), which is then compared to pre-established acute and chronic levels of concern (LOCs) for each category evaluated (Appendix F). For acute exposures to the CRLF and its animal prey in aquatic habitats, as well as terrestrial invertebrates, the LOC is 0.05. For acute exposures to the CRLF and mammals, the LOC is 0.1. The LOC for chronic exposures to CRLF and its prey, as well as acute exposures to plants is 1.0.

Risk to the aquatic-phase CRLF is estimated by calculating the ratio of exposure to toxicity using 1-in-10 year EECs based on the label-recommended myclobutanil usage scenarios summarized in Tables 3.5 and 3.6 and the appropriate aquatic toxicity endpoint from Table 4.1. Risks to the terrestrial-phase CRLF and its prey (*e.g.* terrestrial insects, small mammals and terrestrial-phase frogs) are estimated based on exposures resulting from applications of myclobutanil (Tables 3.9 – 3.10) and the appropriate toxicity endpoint from Table 4.5. Due to lack of toxicity data for myclobutanil, exposures are not estimated for freshwater invertebrates (chronic exposure), aquatic vascular plants, and terrestrial plants.

5.1.1 Exposures in the Aquatic Habitat

Estimated risk for the aquatic habitat is based on a total toxicity approach, that is, EECs for myclobutanil plus 1,2,4-triazole (parent plus degradate) which are higher than the EECs for myclobutanil. There are no aquatic toxicity data available for the primary degradate of myclobutanil (1,2,4-triazole); however, available mammalian studies indicate that it is either less than or equally toxic as the parent. Use of the total toxicity approach for estimating risk was based on two conservative assumptions. First, that the mode of action is the same for 1,2,4-triazole and the parent (myclobutanil) and second that the two compounds are of equivalent toxicity to aquatic organisms.

5.1.1.1 Direct Effects to Aquatic-Phase CRLF

Direct acute effects to the aquatic-phase CRLF are based on peak EECs from the PRZM/EXAMS models and the lowest acute 96-hour LC_{50} toxicity value for freshwater fish. The highest modeled peak EEC is 61.41 ppb (myclobutanil plus 1,2,4 triazole) for the turf scenario (representing turf use). The acute RQ for this scenario is 0.025 which is lower than the acute endangered species LOC of 0.05.

In order to assess direct chronic risks to the CRLF, 60-day EECs from the PRZM/EXAMS models and the lowest chronic toxicity value (NOAEC) for freshwater fish are used. The highest modeled 60-day EEC is 60.71 ppb (myclobutanil plus 1,2,4 triazole) for the turf scenario. The chronic RQ for this scenario is 0.061 which is much lower than the chronic LOC of 1 for fish.

Acute and chronic RQs for all modeled scenarios for myclobutanil and myclobutanil plus 1,2,4 triazole were lower than the related LOC (a summary of the highest RQs is provided in Table 5.1). Based on these results, the effects determination for myclobutanil is "no effect" for direct effects on the aquatic-phase of the CRLF.

Table 5.1 Summary of Acute and Chronic Direct Effect RQs for the Aquatic-phase CRLF

Direct Effects to CRLF	Scenario	EEC (µg/L) [c]	RQ	Probability of Individual Effect at ES LOC[d, e]	Probability of Individual Effect at RQ[d]
Acute Direct Toxicity [a]	Turf	Peak: 61.41	0.025[f]	~1 in 4.18E+8 (~1 in 216 to ~1 in 1.75E+31)	~1 in 3.56E+12 (~1 in 1.48E+3 to ~1 in 5.06E+46)
Chronic Direct Toxicity [b]	Turf	60-day: 60.71	0.061[g]	Not calculated for chronic endpoints	

[a] Based on bluegill sunfish (*Lepomis macrochirus*) acute 96-hour LC_{50} = 2.4 mg/L.
[b] Based on fathead minnow (*Pimephales promelas*) chronic NOAEC = 0.98 mg/L.
[c] From scenario with the highest EECs: granular use on turf (myclobutanil plus 1,2,4-triazole) (see Table 3.6).
[d] The probit dose-response slope value for the bluegill sunfish acute toxicity study is not available; therefore, the effect probability was calculated based on a default slope assumption of 4.5 with upper and lower 95% confidence intervals of 2 and 9 (Urban and Cook, 1986).
[e] Endangered species LOC of 0.05.
[f] RQ < acute endangered species LOC of 0.05.
[g] RQ < chronic LOC of 1.

5.1.1.2 Indirect Effects to Aquatic-Phase CRLF via Reduction in Prey (non-vascular aquatic plants, aquatic invertebrates, fish, and frogs)

a) Non-vascular Aquatic Plants

Indirect effects of myclobutanil to the aquatic-phase CRLF (tadpoles) via reduction in non-vascular aquatic plants in its diet are based on peak EECs from the PRZM/EXAMS models and the lowest toxicity value (EC_{50}) for aquatic non-vascular plants. The most sensitive non-vascular plant 120-hour EC_{50} is 0.83 mg/L (freshwater green algae). The highest modeled peak EEC is 61.41 ppb (myclobutanil plus 1,2,4 triazole) for the turf scenario (representing turf use). The acute RQ for this scenario is 0.074 (61.41 ppb / 830 ppb) which is much lower than the LOC of 1 for aquatic plants.

RQs for all modeled scenarios for myclobutanil and myclobutanil plus 1,2,4 triazole were lower than the aquatic plant LOC. Based on these results, the effects determination for myclobutanil is “no effect” for indirect effects on the CRLF via reduction in non-vascular plants.

b) Aquatic Invertebrates

Indirect acute effects to the aquatic-phase CRLF via effects to prey (invertebrates) in aquatic habitats are based on peak EECs from the PRZM/EXAMS models and the lowest acute toxicity value (LC_{50}) for freshwater invertebrates. The highest modeled peak EEC is 61.41 ppb (myclobutanil plus 1,2,4 triazole) for the turf scenario (representing turf use). The acute RQ for this scenario is 0.005 which is much lower than the acute endangered species LOC of 0.05.

Indirect chronic effects to the aquatic-phase CRLF via effects to prey (invertebrates) cannot be quantitatively estimated because there is currently no chronic invertebrate toxicity data available for myclobutanil.

Acute RQs for all modeled scenarios for myclobutanil and myclobutanil plus 1,2,4 triazole were lower than the endangered species LOC of 0.05 (a summary of the highest RQ is provided in Table 5.2). Based on these results, on an acute basis the effects determination for myclobutanil is “no effect” for indirect effects on the CRLF via reduction in freshwater invertebrates prey items.

Table 5.2 Summary of Acute and Chronic RQs Used to Estimate Indirect Effects to the CRLF via Direct Effects on Aquatic Invertebrates as Dietary Food Items (prey of CRLF juveniles and adults in aquatic habitats)

Direct Effects to Aquatic Invertebrate Prey of CRLF	Scenario	EEC (μg/L) [b]	RQ	% Expected Effect on Prey Population at RQ[c]
Acute Direct Toxicity [a]	Turf	Peak: 61.41	0.005[d]	<0.001 (<0.001 - <0.001)
Chronic Direct Toxicity	Not calculated (no toxicity data available)			

[a] Based on water flea (*Daphnia magna)* acute 48-hour LC_{50} = 11 mg/L.
[b] From scenario with the highest EECs: granular use on turf (myclobutanil plus 1,2,4-triazole) (see Table 3.6)
[c] The % expected effect on prey population was calculated based on a probit dose-response slope of 6.8 (4.1-9.6) for the water flea acute toxicity study.
[d] RQ < acute endangered species LOC of 0.05.

c) Fish and Frogs

Fish and frogs also represent potential prey items of adult aquatic-phase CRLFs. RQs associated with acute and chronic direct toxicity to the CRLF (Table 5.1) are used to assess potential indirect effects to the CRLF based on a reduction in freshwater fish and frogs as food items. Based on the conclusions about direct effects to freshwater fish (see section 5.1.1.1), the effects determination for myclobutanil is “no effect” for indirect effects on the CRLF via reduction in freshwater fish and frogs as food items.

5.1.1.3 Indirect Effects to CRLF via Reduction in Habitat and/or Primary Productivity (Freshwater Aquatic Plants)

Indirect effects to the CRLF via direct toxicity to aquatic plants are estimated using the most sensitive non-vascular and vascular plant toxicity endpoints. The effects determination for myclobutanil is “no effect” for indirect effects on the CRLF via reduction in non-vascular plants (see section 5.1.1.2 for details). Effects to aquatic vascular plants cannot be quantitatively estimated because there is currently no toxicity data available for myclobutanil.

5.1.2 Exposures in the Terrestrial Habitat

5.1.2.1 Direct Effects to Terrestrial-phase CRLF

As previously discussed in Section 3.3, potential direct effects to terrestrial-phase CRLFs are based on foliar and granular applications of myclobutanil. In addition, the RQ calculation for use on cotton seeds assumes that the seeds are 100% available based on shallow planting conditions and an associated planting depth of ½ inch.

Potential direct acute effects to the terrestrial-phase CRLF are derived by considering dose- and dietary-based EECs modeled in T-REX for a small bird (20 g) consuming small invertebrates and acute oral and subacute dietary toxicity endpoints for avian species. Definitive subacute dietary-based RQ values cannot be derived because a statistically meaningful LC_{50} could not be determined as no dose levels resulted in 50% or greater mortality (i.e., mallard duck LC_{50} is > 4090 ppm). Although definitive LC_{50}'s were not derived in the subacute dietary studies, there were mortalities in both studies. The concentration levels at which mortalities were observed will be compared to the terrestrial EECs in the Risk Description section.

Results of the dose-based EEC analysis of direct effects to terrestrial-phase CRLF indicate acute LOC exceedances (RQ > 0.1) for all uses of myclobutanil except Boysenberry/Dewberry/Youngberry (Tables 5.3 and 5.4).

Table 5.3 Summary of Acute RQs Used to Estimate Direct Effects to the Terrestrial-phase CRLF (non-granular application)

Use	Application Rate (lb ai/A)	Dose-based Acute RQ*[1]	Probability of Individual Effect at RQ[2]
Almond	0.2	**0.23**	1 in ~ 2.77E+05
Apple	0.5	**0.70**	1 in ~ 7.24E+00
Apricot	0.5	**0.40**	1 in ~ 3.88E+02
Artichoke	0.1	**0.14**	1 in ~ 1.03E+09
Asparagus	0.125	**0.18**	1 in ~ 1.21E+07
Beans	0.125	**0.18**	1 in ~ 1.21E+07
Blackberry/EggPlant/Okra/Pepper/Raspberry	0.125	**0.16**	1 in ~ 9.04E+07
Boysenberry/Dewberry/Youngberry	0.0625	0.08	1 in ~ 1.54E+14
Carrot	0.1875	**0.14**	1 in ~ 1.03E+09
Canistel/Mango/Papaya/Sapodilla	0.25	**0.39**	1 in ~ 4.95E+02
Cherry/Nectarine/Peach	0.5	**0.56**	1 in ~ 2.61E+01
Cotton	0.06 lb ai/cwt	**0.42**	1 in ~ 2.47E+02
Cucurbit Vegetables	0.12	**0.20**	1 in ~ 2.24E+06
Currant	0.125	**0.19**	1 in ~ 1.21E+07
Gooseberry	0.125	**0.24**	1 in ~ 1.52E+05
Grapes	0.13	**0.24**	1 in ~ 5.03E+06
Hops	0.25	**0.35**	1 in ~ 1.97E+04
Lettuce	0.125	**0.15**	1 in ~ 2.87E+08
Plum/Prune	0.16	**0.33**	1 in ~ 2.81E+03
Tomato	0.1	**0.10**	1 in ~9.62E+11
Turf	1.3	**1.93**	1 in ~ 1

* = LOC exceedances (acute RQ ≥ 0.1) are bolded and shaded.
[1] Based on bobwhite quail acute oral LD50 of 498 mg/kg .
[2] The effect probability was calculated based on a calculated slope of 7.03 with upper and lower 95% confidence intervals of 3.5 and 10.5

Table 5.4 Summary of Acute RQs Used to Estimate Direct Effects to the Terrestrial-phase CRLF (granular application)

Use	Application Rate (lb ai/A)	Dose-based Acute RQ*[1]	Probability of Individual Effect at RQ
Turf	1.35	**1.96**	1 in ~ 1

* = LOC exceedances (acute RQ $\geq$ 0.1) are bolded and shaded.
[1] Based on bobwhite quail acute oral LD50 of 498 mg/kg and a calculated LD50/sq. ft

Potential direct chronic effects of myclobutanil to the terrestrial-phase CRLF are derived by considering dietary-based exposures modeled in T-REX for a small bird (20g) consuming small invertebrates. Chronic effects are estimated using the lowest available toxicity data for birds. EECs are divided by toxicity values to estimate chronic dietary-based RQs. Results of the analysis of direct effects to terrestrial-phase CRLF indicate a chronic LOC exceedance (RQ>1) for turf and cotton use only.

Based on the exceedance of the LOC for the majority of uses after acute exposure and two uses after chronic exposure, myclobutanil may affect directly, the terrestrial-phase of the CRLF.

Table 5.5 Summary of Chronic RQs Used to Estimate Direct Effects to the Terrestrial-phase CRLF (non-granular application)

Use	Application Rate (lb ai/A)	Dietary-based Chronic RQ*[1]
Almond	0.2	0.28
Apple	0.5	0.87
Apricot	0.5	0.49
Artichoke	0.1	0.18
Asparagus	0.125	0.22
Beans	0.125	0.22
Blackberry/EggPlant/Okra/Pepper/Raspberry	0.125	0.20
Boysenberry/Dewberry/Youngberry	0.0625	0.10
Carrot	0.1875	0.17
Canistel/Mango/Papaya/Sapodilla	0.25	0.49
Cherry/Nectarine/Peach	0.5	0.69
Cotton	0.06 lb ai/cwt	**2.34**[2]
Cucurbit Vegetables	0.12	0.24
Currant	0.125	0.23
Gooseberry	0.125	0.23
Grapes	0.13	0.30
Hops	0.25	0.43
Lettuce	0.125	0.18
Plum/Prune	0.16	0.40
Tomato	0.1	0.13
Turf	1.3	**2.38**

* = LOC exceedances (chronic RQ $\geq$ 1) are bolded and shaded.
[1] Based on bobwhite quail NOAEC of 256 ppm.
[2] Planting depth for cotton seeds varies depending on soil moisture and soil texture. The RQ calculation assumes that cotton seeds are 100% available based on shallow planting conditions and an associated planting depth of ½ inch

5.1.2.2 Indirect Effects to Terrestrial-Phase CRLF via Reduction in Prey (terrestrial invertebrates, mammals, and frogs)

5.1.2.2.1 Terrestrial Invertebrates

In order to assess the risks of myclobutanil to terrestrial invertebrates, which are considered prey of CRLF in terrestrial habitats, the honey bee is used as a surrogate for terrestrial invertebrates. The toxicity value for terrestrial invertebrates is calculated by multiplying the lowest available acute contact (dust) LD_{50} of > 363 µg a.i./bee by 1 bee/0.128g, which is based on the weight of an adult honey bee. This is estimated to be >2836 µg a.i./g bw. Because the acute contact effects data shows an LD_{50} of greater than the highest test concentration of 363 µg a.i./bee, definitive acute RQ values cannot be derived. Therefore, a quantitative assessment of risk to terrestrial invertebrates was not conducted. Mortality in the treated bees did not differ from the untreated controls. Given that the honey bee data shows low toxicity, minimal potential indirect impact to the CRLF via effects of myclobutanil on freshwater invertebrate food items is expected. Risk to terrestrial invertebrates will be discussed further in the risk description section.

5.1.2.2.2 Mammals

Risks associated with ingestion of small mammals by large terrestrial-phase CRLFs are derived for dietary-based and dose-based exposures modeled in T-REX for a small mammal (15g) consuming short grass. Acute and chronic effects are estimated using the most sensitive mammalian toxicity data. EECs are divided by the toxicity value to estimate acute and chronic dose-based RQs as well as chronic dietary-based RQs. For granular applications the RQ is based on an estimated LD_{50} per square foot calculated based on application rate and toxicity. For non-granular applications, the acute listed species LOC of 0.1 is exceeded for apple, apricot, cherry/nectarine/peach, canistel/mango/papaya/sapodilla, hops, plum/prune, and turf uses. The chronic LOC of 1 on a dose basis is exceeded for all uses and the chronic LOC on a dietary basis is exceeded for apples, apricots, canistel/mango/papaya/sapodilla, cherry/nectarine/peach, cotton, and turf. For granular uses, the acute listed species LOC is exceeded for turf.

Based on both acute and chronic LOC exceedances for many uses, myclobutanil may affect indirectly, the terrestrial-phase CRLF via reduction in small mammal prey items.

Table 5.6 Summary of Acute and Chronic RQs Used to Estimate Indirect Effects to the Terrestrial-phase CRLF via Direct Effects on Small Mammals as Dietary Food Items (non-granular application)

Use (Application Rate lb ai/acre)	Dose-based Chronic RQ*[1]	Dietary-based Chronic RQ*[2]	Dose-based Acute RQ*[3]	% Expected Effect on Prey Population at RQ [4]
Almond (0.2)	**3.42**	0.63	0.08	9.6
Apple (0.5)	**10.7**	**1.97**	**0.25**	23.7
Apricot (0.5)	**6.09**	**1.12**	**0.14**	15.5
Artichoke (0.1)	**2.18**	0.40	0.05	6.1
Asparagus (0.125)	**2.72**	0.50	0.06	7.3
Beans (0.125)	**2.67**	0.49	0.06	7.3
Blackberry/EggPlant/Okra/Pepper/Raspberry (0.125)	**2.48**	0.46	0.06	7.3
Boysenberry/Dewberry/Youngberry (0.0625)	**1.24**	0.23	0.03	3.5
Carrot (0.1875)	**2.14**	0.40	0.05	6.1
Canistel/Mango/Papaya/Sapodilla (0.25)	**5.99**	**1.10**	**0.14**	15.5
Cherry/Nectarine/Peach (0.5)	**8.55**	**1.58**	**0.20**	20.3
Cotton	NA	**3.00**	NA	NA
Cucurbit Vegetables (0.12)	**3.02**	0.56	0.07	8.5
Currant (0.125)	**2.82**	0.49	0.06	7.3
Gooseberry (0.125)	**3.60**	0.66	0.08	9.6
Grapes (0.13)	**3.69**	0.68	0.09	10.7
Hops (0.25)	**5.35**	0.99	**0.12**	13.7
Lettuce (0.125)	**2.25**	0.42	0.05	6.1
Plum/Prune (0.16)	**5.00**	0.92	**0.12**	13.7
Tomato (0.1)	**1.55**	0.29	0.04	4.8
Turf (1.3)	**29.35**	**5.41**	**0.68**	42.1

* = LOC exceedances (acute RQ ≥ 0.1; chronic RQ ≥ 1) are bolded and shaded
[1] Based on dose-based EEC and myclobutanil rat NOAEL = 16 mg/kg-bw.
[2] Based on dietary-based EEC and myclobutanil rat NOAEC = 200 mg/kg-diet.
[3] Based on dose-based EEC and myclobutanil mouse acute oral LD_{50} = 1360 mg/kg-bw.
[4] % expected effect on prey population at RQ is calculated using the acute mouse toxicity study probit dose-response slope of 1.19. No confidence interval was provided.

Table 5.7 Summary of Acute RQs Used to Estimate Indirect Effects to the Terrestrial-phase CRLF via Direct Effects on Small Mammals as Dietary Food Items (granular application)

Use	Application Rate (lb ai/A)	Dose-based Acute RQ*[1]	% Expected Effect on Prey Population at RQ
Turf	1.35	**0.63**	40.2

* = LOC exceedances (acute RQ ≥ 0.1) are bolded and shaded.
[1] Based and adjusted LD_{50} of 1380 mg/kg and a calculated LD_{50}/sq. ft

5.1.2.2.3 Frogs

An additional prey item of the adult terrestrial-phase CRLF is other species of frogs. In order to assess risks to these organisms, dietary-based and dose-based exposures modeled in T-REX for a small bird (20g) consuming small invertebrates are used. See Section 5.1.2.1 and associated tables for results. The acute LOC for listed species is exceeded for the majority of myclobutanil uses. The chronic LOC is exceeded for cotton and turf. Therefore, following both acute and chronic exposure myclobutanil may affect indirectly, the CRLF via reduction in frogs as prey items.

5.1.2.3 Indirect Effects to CRLF via Reduction in Terrestrial Plant Community (Riparian and Upland Habitat)

Indirect effects to the CRLF via reduction in terrestrial plant community cannot be quantitatively estimated because there are no vegetative vigor or seedling emergence plant toxicity data available for myclobutanil. For a qualitative risk description, see Section 5.2.3.2.

5.1.3 Primary Constituent Elements of Designated Critical Habitat

For myclobutanil use, the assessment endpoints for designated critical habitat PCEs involve a reduction and/or modification of food sources necessary for normal growth and viability of aquatic-phase CRLFs, and/or a reduction and/or modification of food sources for terrestrial-phase juveniles and adults. Because these endpoints are also being assessed relative to the potential for indirect effects to aquatic- and terrestrial-phase CRLF, the effects determinations for indirect effects from the potential loss of food items are used as the basis of the effects determination for potential effects to designated critical habitat.

5.1.3.1 Aquatic-Phase (Aquatic Breeding Habitat and Aquatic Non-Breeding Habitat)

Three of the four assessment endpoints for the aquatic-phase primary constituent elements (PCEs) of designated critical habitat for the CRLF are related to potential effects to aquatic and/or terrestrial plants:

- Alteration of channel/pond morphology or geometry and/or increase in sediment deposition within the stream channel or pond: aquatic habitat (including riparian vegetation) provides for shelter, foraging, predator avoidance, and aquatic dispersal for juvenile and adult CRLFs.
- Alteration in water chemistry/quality including temperature, turbidity, and oxygen content necessary for normal growth and viability of juvenile and adult CRLFs and their food source.
- Reduction and/or modification of aquatic-based food sources for pre-metamorphs (*e.g.*, algae).

Based on the risk estimation for potential effects to aquatic non-vascular plants provided in Section 5.1.1.2, myclobutanil is expected to have no effect on aquatic-phase PCEs of designated habitat related to effects on aquatic non-vascular plants. The highest modeled peak EEC for turf use (61.41 ppb) and the most sensitive non-vascular plant endpoint (830 ppb) provide an aquatic non-vascular plant RQ of 0.074, which is much lower than the LOC of 1 for aquatic plants. Therefore, the RQs for all scenarios will be less than the LOC for aquatic plants.

Risk estimations for potential effects to aquatic vascular plants and terrestrial plants were not conducted because no toxicity data are available for myclobutanil. Therefore, it cannot be estimated whether or not myclobutanil is likely to affect aquatic-phase PCEs of designated habitat related to effects on aquatic vascular plants and terrestrial plants. Risks to aquatic vascular plants and terrestrial plants will be discussed qualitatively in Section 5.2.3.

The remaining aquatic-phase PCE is "alteration of other chemical characteristics necessary for normal growth and viability of CRLFs and their food source." To assess the impact of myclobutanil on this PCE (*i.e.*, alteration of food sources), acute and chronic freshwater fish and invertebrate toxicity endpoints, as well endpoints for aquatic non-vascular plants, are used as measures of effects. RQs for these endpoints were calculated in Sections 5.1.1.1 and 5.1.1.2. Based on acute RQs for freshwater fish and invertebrates and for non-vascular plants that are less than the LOCs for all uses, myclobutanil is expected to have no effect on aquatic-phase PCEs of designated habitat related to effects of alteration of other chemical characteristics necessary for normal growth and viability of CRLFs and their food source. Following chronic exposure, data are only available for freshwater fish. For all uses, the chronic RQs for freshwater fish are less than the LOC. Therefore, following chronic exposure, it can only be partially estimated whether or not myclobutanil is likely to affect aquatic-phase PCEs of designated habitat related to effects of alteration of other chemical characteristics necessary for normal growth and viability of CRLFs and their food source. Based on chronic effects to freshwater fish, myclobutanil is expected to have no effect on this PCE. Chronic risk to freshwater invertebrates will be discussed qualitatively in section 5.2.2.2.

5.1.3.2 Terrestrial-Phase (Upland Habitat and Dispersal Habitat)

The first two assessment endpoints for the terrestrial-phase PCEs of designated critical habitat for the CRLF are related to potential effects to terrestrial plants:

- Elimination and/or disturbance of upland habitat; ability of habitat to support food source of CRLFs: Upland areas within 200 ft of the edge of the riparian vegetation or dripline surrounding aquatic and riparian habitat that are comprised of grasslands, woodlands, and/or wetland/riparian plant species that provides the CRLF shelter, forage, and predator avoidance
- Elimination and/or disturbance of dispersal habitat: Upland or riparian dispersal habitat within designated units and between occupied locations within 0.7 mi of each other that allow for movement between sites including both natural and altered sites which do not contain barriers to dispersal

The risk estimation for terrestrial-phase PCEs of designated habitat related to potential effects on terrestrial plants cannot be quantitatively addressed because there are no vegetative vigor or seedling emergence plant toxicity data available for myclobutanil. The risk will be discussed qualitatively in Section 5.2.3.2.

The third terrestrial-phase PCE is "reduction and/or modification of food sources for terrestrial phase juveniles and adults." To assess the impact of myclobutanil on this PCE, acute and chronic toxicity endpoints for birds, mammals, and terrestrial invertebrates are used as measures of effects. RQs for these endpoints were calculated in Sections 5.1.2.1 and 5.1.2.2. For terrestrial-phase amphibians, using birds as a surrogate, there are acute LOC listed species exceedances for multiple uses. The chronic avian LOC is exceeded for turf and cotton uses. RQs for terrestrial invertebrates were not estimated because a definitive LD_{50} was not available. For mammals, the acute LOC for listed species is exceeded for multiple crops and the acute LOC for non-listed species is exceeded for turf. The chronic LOC is exceeded for multiple crops. Therefore, myclobutanil may affect the third terrestrial-phase PCE.

The fourth terrestrial-phase PCE is based on alteration of chemical characteristics necessary for normal growth and viability of juvenile and adult CRLFs and their food source. Direct acute and chronic RQs for terrestrial-phase CRLFs are presented in Section 5.1.2.1. Again, the acute LOC is exceeded for multiple uses and the chronic LOC for cotton and turf uses. The same acute and chronic RQ estimates are used for indirect effects based on terrestrial-phase amphibians as a food source. For other prey species, RQs for terrestrial invertebrates were not estimated because a definitive LD_{50} was not available. For mammals, the acute LOC for listed species is exceeded for multiple crops and the acute LOC for non-listed species is exceeded for turf. The chronic LOC is exceeded for multiple crops. Therefore, myclobutanil may affect the fourth terrestrial-phase PCE.

5.2 Risk Description

The risk description synthesizes an overall conclusion regarding the likelihood of adverse impacts leading to an effects determination (*i.e.*, "no effect," "may affect, but not likely to adversely affect," or "likely to adversely affect") for the CRLF and its designated critical habitat.

Based on the RQs presented in the Risk Estimation (Section 5.1) a preliminary effects determination is may affect for the CRLF and critical habitat.

Direct/indirect effect LOCs are exceeded and myclobutanil use may affect the PCEs of the CRLF's critical habitat. Therefore, the Agency concludes a preliminary "may affect" determination for the FIFRA regulatory action regarding myclobutanil. A summary of the risk estimation results are provided in Table 5.8 for direct and indirect effects to the CRLF and in Table 5.9 for the PCEs of designated critical habitat for the CRLF.

Table 5.8 Risk Estimation Summary for Myclobutanil - Direct and Indirect Effects to CRLF

Assessment Endpoint	LOC Exceedances (Y/N)	Description of Results of Risk Estimation
Aquatic Phase (eggs, larvae, tadpoles, juveniles, and adults)		
Direct Effects Survival, growth, and reproduction of CRLF individuals via direct effects on aquatic phases	N	There are no LOC exceedences for listed species following both acute and chronic exposure using freshwater fish as the surrogate for aquatic-phase amphibians.
Indirect Effects Survival, growth, and reproduction of CRLF individuals via effects to food supply (*i.e.*, freshwater invertebrates, non-vascular plants)	Unknown	There are no LOC exceedences for listed species following acute exposure to freshwater invertebrates. No chronic exposure data are available. A qualitative discussion of risk is provided. There are no LOC exceedences for aquatic non-vascular plants.
Indirect Effects Survival, growth, and reproduction of CRLF individuals via effects on habitat, cover, and/or primary productivity (*i.e.*, aquatic plant community)	Unknown	There are no LOC exceedences for aquatic non-vascular plants. No aquatic vascular plant data are available. A qualitative discussion of risk is provided.
Indirect Effects Survival, growth, and reproduction of CRLF individuals via effects to riparian vegetation, required to maintain acceptable water quality and habitat in ponds and streams comprising the species' current range.	Unknown	No vegetative vigor or seedling emergence plant toxicity data are available. A qualitative discussion of risk is provided.
Terrestrial Phase (Juveniles and adults)		
Direct Effects Survival, growth, and reproduction of CRLF individuals via direct effects on terrestrial phase adults and juveniles	Y	For the terrestrial-phase CRLF, birds are used as a surrogate. There are dose-based acute LOC exceedances (RQ > 0.1) for all uses except Boysenberry/Dewberry/Youngberry. The chronic avian LOC is exceeded for turf and cotton uses.
Indirect Effects Survival, growth, and reproduction of CRLF individuals via effects on prey (*i.e.*, terrestrial invertebrates, small terrestrial mammals and terrestrial phase amphibians)	Y	For mammals following non-granular applications, the acute listed species LOC is exceeded for apple, apricot, cherry, nectarine, peach, hops and turf uses. The chronic LOC on a dose basis is exceeded for all uses and the chronic LOC on a dietary basis is exceeded for apples, apricots, cherries, nectarines, peaches, cotton and turf. For granular uses, the acute listed species LOC is exceeded for turf. For terrestrial invertebrates, the acute contact LD_{50} is greater than the highest dose tested. In addition, there were no mortalities. Risk the terrestrial invertebrates will be discussed qualitatively in the risk description. For terrestrial-phase amphibians, birds are used as a surrogate. For birds, There are dose-based acute LOC exceedances (RQ > 0.1) for all uses except Boysenberry/Dewberry/Youngberry. The chronic avian LOC is

Assessment Endpoint	LOC Exceedances (Y/N)	Description of Results of Risk Estimation
		exceeded for turf and cotton uses.
Indirect Effects Survival, growth, and reproduction of CRLF individuals via effects on habitat (*i.e.*, riparian vegetation)	Unknown	No vegetative vigor or seedling emergence plant toxicity data are available. A qualitative discussion of risk is provided.

Table 5.9 Risk Estimation Summary for Myclobutanil – PCEs of Designated Critical Habitat for the CRLF

Assessment Endpoint	Habitat Effects (Y/N)	Description of Results of Risk Estimation
Aquatic Phase PCEs (Aquatic Breeding Habitat and Aquatic Non-Breeding Habitat)		
Alteration of channel/pond morphology or geometry and/or increase in sediment deposition within the stream channel or pond: aquatic habitat (including riparian vegetation) provides for shelter, foraging, predator avoidance, and aquatic dispersal for juvenile and adult CRLFs.	Unknown	There are no LOC exceedences for aquatic non-vascular plants. No aquatic vascular or terrestrial plant data are available. A qualitative discussion of risk is provided.
Alteration in water chemistry/quality including temperature, turbidity, and oxygen content necessary for normal growth and viability of juvenile and adult CRLFs and their food source.	Unknown	There are no LOC exceedences for aquatic non-vascular plants. No aquatic vascular or terrestrial plant data are available. A qualitative discussion of risk is provided.
Alteration of other chemical characteristics necessary for normal growth and viability of CRLFs and their food source.	Unknown	There are no LOC exceedences for listed species following acute and chronic exposure to freshwater fish or acute exposure to freshwater invertebrates. There are no LOC exceedences for aquatic non-vascular plants. No data are available for freshwater invertebrates (chronic exposure) or aquatic vascular plants. A qualitative discussion of risk is provided.
Reduction and/or modification of aquatic-based food sources for pre-metamorphs (e.g., algae)	N	There are no LOC exceedences for aquatic non-vascular plants.
Terrestrial Phase PCEs (Upland Habitat and Dispersal Habitat)		
Elimination and/or disturbance of upland habitat; ability of habitat to support food source of CRLFs: Upland areas within 200 ft of the edge of the riparian vegetation or dripline surrounding aquatic and riparian habitat that are comprised of grasslands, woodlands, and/or wetland/riparian plant species that provides the CRLF shelter, forage, and predator avoidance	Unknown	No vegetative vigor or seedling emergence plant toxicity data are available. A qualitative discussion of risk is provided.
Elimination and/or disturbance of dispersal habitat: Upland or riparian dispersal habitat	Unknown	No vegetative vigor or seedling emergence plant toxicity data are available. A qualitative discussion

Assessment Endpoint	Habitat Effects (Y/N)	Description of Results of Risk Estimation
within designated units and between occupied locations within 0.7 mi of each other that allow for movement between sites including both natural and altered sites which do not contain barriers to dispersal		of risk is provided.
Reduction and/or modification of food sources for terrestrial phase juveniles and adults	Y	For mammals, the acute and chronic LOCs are exceeded for multiple crops. For terrestrial invertebrates, the acute contact LD_{50} is greater than the highest dose tested with no mortalities. Risk the terrestrial invertebrates will be discussed qualitatively in the risk description. For terrestrial-phase amphibians, birds are used as a surrogate. Acute and chronic LOCs are exceeded for multiple crops.
Alteration of chemical characteristics necessary for normal growth and viability of juvenile and adult CRLFs and their food source.	Y	See above box.

Following a “may affect” determination, additional information is considered to refine the potential for exposure at the predicted levels based on the life history characteristics (*i.e.*, habitat range, feeding preferences, etc.) of the CRLF. Based on the best available information, the Agency uses the refined evaluation to distinguish those actions that “may affect, but are not likely to adversely affect” from those actions that are “likely to adversely affect” the CRLF and its designated critical habitat.

The criteria used to make determinations that the effects of an action are “not likely to adversely affect” the CRLF and its designated critical habitat include the following:

- Significance of Effect: Insignificant effects are those that cannot be meaningfully measured, detected, or evaluated in the context of a level of effect where “take” occurs for even a single individual. “Take” in this context means to harass or harm, defined as the following:
    - Harm includes significant habitat effects or degradation that results in death or injury to listed species by significantly impairing behavioral patterns such as breeding, feeding, or sheltering.
    - Harass is defined as actions that create the likelihood of injury to listed species to such an extent as to significantly disrupt normal behavior patterns which include, but are not limited to, breeding, feeding, or sheltering.
- Likelihood of the Effect Occurring: Discountable effects are those that are extremely unlikely to occur.
- Adverse Nature of Effect: Effects that are wholly beneficial without any adverse effects are not considered adverse.

A description of the risk and effects determination for each of the established assessment endpoints for the CRLF and its designated critical habitat is provided in Sections 5.2.1 through 5.2.3

5.2.1 Direct Effects

5.2.1.1 Aquatic-Phase CRLF

The aquatic-phase considers life stages of the frog that are obligatory aquatic organisms, including eggs and larvae. It also considers submerged terrestrial-phase juveniles and adults, which spend a portion of their time in water bodies that may receive runoff and spray drift containing myclobutanil.

Acute and chronic RQs for all modeled scenarios for myclobutanil and myclobutanil plus 1,2,4 triazole were lower than the related LOC. The highest acute RQ was 0.025 and the highest chronic RQ was 0.061, both RQs based on the turf scenario. The probability of an individual effect at the highest RQ (turf scenario) is estimated to be 1 in 3.56×10^{12} (1 in 1.48×10^{3} to 1 in 5.06×10^{46}, 95% C.I.) based on a default slope assumption of 4.5 (2 to 9, 95% C.I.)

Water monitoring and rainfall data support the risk conclusions based on RQs calculated with modeled EECs. The available non-targeted monitoring data show myclobutanil concentrations that are much lower than the modeled concentrations. The highest concentrations of myclobutanil were detected in surface water. Myclobutanil was detected in ambient surface water (Table 3.3) at a detection frequency of 37.8 % (166 of 439 samples) collected in five counties in California. The maximum daily myclobutanil concentration was 0.507 μg/L for a sampling site (USGS Sampling Station 373112120382901) located near Montpelier California in Merced County California. In comparison to surface water monitoring data which did not include 1,2,4-triazole, the lowest modeled concentrations of myclobutanil (plus 1,2,4 triazole) were 2.84 μg/L (peak), 2.82 μg/L (21-day), and 2.77 μg/L (60-day).

There are no relevant data in the open literature and no incident data for fish.

The effects determination is no effect on aquatic-phase CRLF from direct exposures to myclobutanil.

5.2.1.2 Terrestrial-Phase CRLF

As stated in the Risk Estimation section (Section 5.1.2.1), the acute avian dose-based RQs exceed the acute LOC for listed species (0.1) for all uses of myclobutanil except boysenberry/dewberry/youngberry at an application rate of 0.0625 lbs. a.i./A. In an effort to refine the acute dose-based risk estimates, the T-REX model was modified to account for the lower metabolic rate and lower caloric requirement of amphibians (compared to birds). Acute dose-based RQs were recalculated using the T-HERPS (Version 1.0) model for small (1 g), medium (37 g), and large (238 g) frogs. An example output from T-HERPS is in Appendix M. Using this refinement, the acute dose-based RQ exceeds the acute listed species LOC of 0.1 for 238 gram amphibians eating small herbivorous mammals following application to turf. The dose-based RQs for 37 gram amphibians eating small herbivorous mammals exceed the acute LOC for listed species following application to all crops except boysenberry/dewberry/youngberry at an application rate of 0.0625 lbs a.i./A and tomatoes at 0.1 lbs a.i./A (see Table 5.10).

Table 5.10 Thirty Seven Gram Amphibian T-HERPS RQs for Consumption of Small Herbivorous Mammals

USE	RQ
Almond	**0.16**
Apple	**0.49**
Apricot	**0.28**
Artichoke	**0.10**
Asparagus	**0.13**
Beans	**0.12**
Blackberry/EggPlant/Okra/Pepper/Raspberry	**0.11**
Boysenberry/Dewberry/Youngberry	0.06
Carrot	**0.10**
Canistel/Mango/Papaya/Sapodilla	**0.28**
Cherry/Nectarine/Peach	**0.39**
Cucurbit Vegetables	**0.14**
Currant	**0.13**
Gooseberry	**0.17**
Grapes	**0.13**
Hops	**0.25**
Lettuce	**0.10**
Plum/Prune	**0.23**
Tomato	0.07
Turf	**1.41**

1 **Bold** indicates that the RQ exceeds the listed species LOC of 0.1
2 T-HERPS turf use RQ for 238 gram amphibians consuming small herbivorous mammals = 0.22, which exceeds the acute listed species LOC of 0.1

In the acute oral study with Bobwhite quail (MRID 00144286), lethargy and anorexia were observed in all birds at all dose levels. The lowest dose level tested was 316 mg/kg bw. These symptoms lasted until death in the two highest test doses (1000 and 1470 mg/kg bw), seven days at 681 mg/kg bw, three days at 464 mg/kg bw, and two days at the lowest dose. All birds except for one each in the 1000 and 681 mg/kg bw groups showed distention of the crop containing either test material or air, and food. Five birds (two from the 464 mg/kg group and one each from the 681, 1000 and 1470 mg/kg groups) showed microscopic findings in liver and intestinal tissues. Three of the surviving birds showed microscopic findings in liver and intestinal tissues. Since all birds were affected in this study, no NOAEL could be established. The lowest dose tested (316 mg/kg bw) corresponds to an adjusted dose of 228 mg/kg bw for a 20 gram bird. For the turf use, the dose-based EEC for small insects is 693 mg/kg bw, which is higher than the lowest dose tested adjusted for a 20 gram bird. The dose-based EEC for small insects is also greater than the lowest adjusted dose tested. None of the other uses generated dose-based EECs for small insects that were greater than the lowest adjusted dose tested. The dose-based EECs ranged from 29 for Boysenberry/Dewberry/Youngberry to 693 for turf (see Table 3.9 in Section 3.3). Since there were effects at the lowest dose, there is an uncertainty associated with potential sublethal effects in birds on a dose-basis for all the uses.

The probability of an individual effect on a dose-basis ranges from 1 in ~ 1.54E+14 for uses on boysenberry/dewberry/youngberry to 1 in ~ 1 for use on turf. The highest probabilities are for uses on turf, apples (1 in ~ 7.24E+00), cherries/nectarines/peaches (1 in ~ 2.61E+01), canistel/mango/papaya/sapodilla (1 in ~ 4.95E+02) and apricots (1 in ~ 3.88E+02).

RQs on an acute dietary basis were not estimated because the LC_{50} value exceeds the maximum limit concentration tested. As stated in the effects section, myclobutanil is categorized as slightly toxic on a dietary basis with subacute dietary LC_{50}'s of >4090 ppm for mallard ducks (MRID 00144288) and > 4530 ppm for bobwhite quail (MRID 00144287). Although no definitive subacute dietary LC_{50}'s could be determined from these studies, there were mortalities in both studies. There was one mortality at 4090 ppm, the highest concentration tested in mallard ducks and mortalities at 3000 ppm and 4530 ppm, the highest concentrations tested in bobwhite quail. The estimated dietary-based EEC for small insects following use on turf is 609 ppm, which is roughly 4.9 times lower than 3000 ppm, the lowest concentration where mortality was observed (*e.g.*, the upper bound subacute dietary based RQ would be 0.2). This value is greater than the avian acute risk to listed species LOC of 0.1. Therefore, there is an uncertainty associated with potential mortality to listed species following turf uses. For apples, which have the next highest terrestrial exposure on a dietary basis the EEC is 222 ppm for small insects, which is 13.5 times less than the lowest concentration where mortality was observed (e.g., the upper bound subacute dietary based RQ would be 0.07). This is less than the acute avian LOC for listed species.

As stated in the Risk Estimation section, the chronic avian LOC is exceeded following use on turf and cotton (assuming 100% of seed available). None of the other uses generated chronic RQs that exceeded the chronic LOC.

There were no avian or amphibian studies available in the ECOTOX open literature for myclobutanil. Similarly, no myclobutanil incidents have been reported involving birds or terrestrial-phase amphibians.

The Agency concludes that there is a potential direct impact to the terrestrial-phase CRLF. The effects determination is likely to adversely affect based on the weight of the evidence as follows:

- Acute dose-based RQs estimated from T-HERPS exceed the acute LOC of 0.1 for listed species for both 37 and 238 gram amphibians eating small herbivorous mammals following application to turf. The dose-based RQs for 37 gram amphibians eating small herbivorous mammals exceed the acute LOC for listed species following application to all crops except boysenberry/dewberry/youngberry and tomatoes.
- On an acute dose-basis, there is an uncertainty associated with potential sublethal effects for all uses.
- Based on the lowest dietary concentration where mortality was observed in the subacute dietary studies (both studies had LC_{50}'s greater than the highest concentration tested), there is an uncertainty associated with potential mortality to listed species following turf uses.
- The highest probabilities of an individual effect on a dose-basis are for uses on turf (1 in ~ 1), apples (1 in ~ 7.24E+00), cherries/nectarines/peaches (1 in ~ 2.61E+01), canistel/mango/papaya/sapodilla (1 in ~ 4.95E+02) and apricots (1 in ~ 3.88E+02).
- The chronic avian LOC is exceeded following use on turf and cotton (assuming 100% of seed available).

5.2.2 Indirect Effects (via Reductions in Prey Base)

5.2.2.1 Algae (non-vascular plants)

As discussed in Section 2.5.3, the diet of CRLF tadpoles is composed primarily of unicellular aquatic plants (i.e., algae and diatoms) and detritus. Acute RQs for aquatic non-vascular plants did not exceed the LOC of 1 for any of the assessed uses. The highest acute RQ (0.074) was for the turf scenario. As previously discussed, available monitoring data show myclobutanil concentrations that are much lower than the modeled concentrations. There are no relevant data in the open literature and no incident data for aquatic plants. The effects determination is no effect on indirect impact to the CRLF via effects of myclobutanil on algal food items.

5.2.2.2 Aquatic Invertebrates

The potential for myclobutanil to elicit indirect effects to the CRLF via effects on freshwater invertebrate food items is dependent on several factors including: (1) the potential magnitude of effect on freshwater invertebrate individuals and populations; and (2) the number of prey species potentially affected relative to the expected number of species needed to maintain the dietary needs of the CRLF. Together, these data provide a basis to evaluate whether the number of individuals within a prey species is likely to be reduced such that it may indirectly affect the CRLF.

No acute RQs exceeded the endangered species LOC of 0.05. The highest acute RQ for aquatic invertebrates was 0.005 (turf scenario). At this RQ, the percent effect to the aquatic invertebrate prey base is < 0.001% (i.e. the percentage of the aquatic invertebrate population that may be affected following exposure to myclobutanil).

No chronic freshwater invertebrate toxicity data are available for myclobutanil. It was not possible to estimate a chronic toxicity value for freshwater invertebrates using an acute to chronic ratio with estuarine/marine invertebrate data because no chronic studies are available for myclobutanil. Therefore, a quantitative assessment of risk following chronic exposure to myclobutanil was not possible using these methods. However, the risk may be considered using other approaches.

Using the modeled EECs, freshwater invertebrate chronic toxicity values that would trigger an exceedence of the LOC can be calculated for myclobutanil. The highest 21-day EEC modeled is 61.15 ug/L (turf scenario). Based on that value, for myclobutanil a chronic toxicity value of ≤ 0.061 mg/L would exceed the LOC of 1. In the context of the acute toxicity of myclobutanil to aquatic invertebrates (11 mg/L), a chronic toxicity value ≤ 0.061 mg/L would yield an acute to chronic ratio of ≥180.

As previously described, acute and chronic toxicity data from other conazole (DMI triazole) fungicides were available for aquatic invertebrates. For risk description purposes, these endpoints were used to calculate acute to chronic ratios, assuming that myclobutanil toxicity is similar to other conazoles due to similar mode of action. Data were available for nine conazole to calculate acute to chronic ratios from water flea (*Daphnia magna*) studies (the species which acute data is available for myclobutanil).

As applied to myclobutanil, only one of the conazole acute-to-chronic ratios (high-end estimate for cyproconazole = 1368) is higher that the ratio of ≥180 that would trigger chronic LOC exceedences for freshwater invertebrates based on myclobutanil modeled EECs. Assuming an acute-to-chronic ratio of 1368, chronic toxicity of myclobutanil to freshwater invertebrates is estimated to be 8.04 µg/L. Based on this high-end estimate for cyproconazole, RQs based on the 21-day EEC of myclobutanil plus 1,2,4 triazole range from 0.35 to 7.61. Nearly all uses exceed the chronic LOC of 1; only those with 21-day EECs less than 8.04 µg/L do not exceed (see Table 3.6). It is important to note that there were two available chronic toxicity studies for cyproconazole. The NOAEC/LOAECs for these two studies are: 0.019/0.073 and 0.29/0.57 mg/L, respectively. Both studies are acceptable for assessment of risk, but the one with the lower endpoints was graded as supplemental and was a static study. The other study with the higher endpoints was graded acceptable and was a flow-through study. The low end cyproconazole acute-to-chronic ratio estimate (89.6) is less than the ratio of ≥180 that would trigger LOC exceedences for myclobutanil. Thus, as applied to myclobutanil there are no exceedences of the LOC based on the lower end acute-to-chronic estimate for cyproconazole. Cyproconazole toxicity data suggests the possibility of effects from myclobutanil on freshwater invertebrates that may exceed the LOC. However, there is considerable uncertainty associated with extrapolating toxicity from other conazoles to myclobutanil including the high variability among conazole acute-to-chronic ratios (range from 2.4 to 1368). Thus, the effects of myclobutanil cannot be quantified without data on myclobutanil toxicity to aquatic invertebrates.

In addition to studies on the water flea (*Daphnia magna*), four of the conazoles had studies submitted for other aquatic invertebrate taxa. For these four conazoles, *Daphnia magna* was the most sensitive aquatic invertebrate species tested.

As previously discussed, available monitoring data show myclobutanil concentrations that are much lower than the modeled concentrations. It was observed that the Tier II EECs indicated year-to-year accumulation of myclobutanil in the standard pond model. However, this accumulation is not unexpected due to the persistence of myclobutanil and myclobutanil plus 1,2,4-triazole in soil and water environments, and the lack of inflow and outflow in the standard pond model that precludes decreases in concentrations of residues due to dilution. Therefore, the accumulation is conservative (an overestimate) compared to flowing systems. Furthermore, the K_{oc} is probably not high enough for accumulation in the sediment to be much of an issue.

There are no acceptable open literature data available or reported aquatic invertebrate incidents attributed myclobutanil.

Based on the weight of evidence, there is minimal potential indirect impact to the CRLF via effects of myclobutanil on freshwater invertebrate food items. The effects determination is no effect on an acute basis and may effect, not likely to adversely affect on a chronic basis.

5.2.2.3 Fish and Aquatic-phase Frogs

Myclobutanil is moderately toxic on an acute basis to freshwater fish, the surrogate for the aquatic-phase CRLF. The acute and chronic RQs for all modeled scenarios for myclobutanil and myclobutanil plus 1,2,4 triazole were lower than the related LOC. The probability of an individual effect at the highest RQ (turf scenario) is estimated to be 1 in 3.56×10^{12} (1 in 1.48×10^{3} to 1 in 5.06×10^{46}, 95% C.I.) based on a default slope assumption of 4.5 (2 to 9, 95% C.I.). Water monitoring and rainfall data support the risk conclusions based on RQs calculated with modeled EECs. Available monitoring data show myclobutanil concentrations that are much lower than the modeled concentrations. There are no relevant data in the open literature and no incident data for fish. The effects determination is myclobutanil has “no effect” on indirectly impacting the aquatic-phase CRLF based on the endpoints generated from the freshwater fish data.

5.2.2.4 Terrestrial Invertebrates

When the terrestrial-phase CRLF reaches juvenile and adult stages, its diet is mainly composed of terrestrial invertebrates. As stated in the risk estimation section (Section 5.1.2), the acute RQs for terrestrial invertebrates were not estimated because no definitive LC_{50} can be estimated from the available data. The data indicate no mortalities at concentration levels up to and including 2836 µg a.i./g bw or 2836 ppm (highest level tested) in the acute contact study with honey bees. The estimated dietary-based EEC for small insects with the use on turf is 608.82 ppm, which is 4.7 times lower than 2836 ppm (e.g., the upper bound acute RQ would be 0.21). This value is higher than the acute LOC of 0.05 for listed terrestrial invertebrate species. Upper bound RQs for small insects would also slightly exceed the acute LOC for apple (RQ = 0.08) and cherry, nectarine and peach uses (RQ = 0.06). Estimated upper bound small insect RQs for all other uses are below the LOC. Based on the above estimates for small insects, there is an uncertainty associated with potential mortality for listed terrestrial invertebrates. The estimated dietary-based EEC for large insects with the use on turf is 67.65 ppm. This is 41 times lower than 2836 ppm (upper bound RQ of 0.02). This value is lower than the acute LOC of 0.05 for listed terrestrial invertebrate species and thus, there is no concern for listed large invertebrates for any of the myclobutanil uses.

As noted in Section 4.2 on toxicity to terrestrial organisms, one of the five available literature studies on terrestrial invertebrates provided an LD_{50}. Three mite studies and one arthropod study showed no adverse effects on the species evaluated. A single study on mirids provided an LD_{50} of 150 µg ai/L to adult mirids. The study did not show toxicity to nymphs. A quantitative analysis of potential risk to terrestrial invertebrates based on the LD_{50} for mirids cannot be conducted, however, because insufficient data are available to calculate ppm exposures (i.e., data on the weight of the organism are not available). However, based on the results of the honey bee study, the absence of adverse effects in four of the five available literature studies, and the fact that the mirid study showed no toxicity to nymphs, minimal potential indirect impact to the CRLF via effects of myclobutanil on freshwater invertebrate food items is expected. The effects determination is may affect, not likely to adversely affect.

5.2.2.5 Mammals

Life history data for terrestrial-phase CRLFs indicate that large adult frogs consume terrestrial vertebrates, including mice. The dose-based chronic RQs exceed the listed species chronic LOC for all uses and the dietary-based chronic RQs for a number of myclobutanil uses. The dose-based acute RQs also exceed the listed species acute RQs for a number of uses. The chronic dietary-based RQ exceedances range from 1.1 for uses of myclobutanil on canistel, mango, papaya and sapodilla to 5.4 for uses on turf. Chronic dose-based RQs range from 1.24 (caneberries) to 29.35 (turf). Acute dose-based RQ exceedances range from 0.12 (plums and hops) to 0.68 (turf). At the lowest acute RQ exceedance of 0.12 for hops and plums, the expected effect on the prey population is 13.7% based on a default slope factor of 1.19. The highest acute RQ exceedance for turf of 0.68 corresponds with an expected effect on the prey population of 42%. As noted in Section 4.2, the 60 DF myclobutanil formulation was identified as potentially more toxic than the technical material based on a rat LD_{50} of 980 mg formulation/kg bw for the 60 DF product. The 60 DF formulation is used only on apple and grape crops. Therefore, RQs were derived using the rat LD_{50} for the 60 DF formulation for apples (RQ = 0.21) and grapes (RQ = 0.05). These results indicate that based on actual use parameters, the 60 DF formulation does not present higher toxicity in the field than other formulations when applied at label prescribed rates. Based on the weight-of-evidence, uses for myclobutanil may indirectly impact the CRLF through effects to the mammalian prey base. The effects determination is likely to adversely affect.

5.2.2.6 Terrestrial-phase Amphibians

Terrestrial-phase adult CRLFs also consume frogs. RQ values representing direct exposures of myclobutanil to terrestrial-phase CRLFs are used to represent exposures of myclobutanil to frogs in terrestrial habitats. Based on the assessment of risk to the terrestrial-phase CRLF (direct effects), the Agency concludes that myclobutanil may indirectly impact the CRLF through effects to the terrestrial-phase amphibian prey base. The effects determination is likely to adversely affect (see Section 5.2.1.2 for more details).

5.2.3 Indirect Effects (via Habitat Effects)

5.2.3.1 Aquatic Plants (Vascular and Non-vascular)

Aquatic plants serve several important functions in aquatic ecosystems. Non-vascular aquatic plants are primary producers and provide the autochthonous energy base for aquatic ecosystems. Vascular plants provide structure as attachment sites and refugia for many aquatic invertebrates, fish, and juvenile organisms, such as fish and frogs. In addition, vascular plants also provide primary productivity and oxygen to the aquatic ecosystem. Rooted plants help reduce sediment loading and provide stability to nearshore areas and lower streambanks. In addition, vascular aquatic plants are important as attachment sites for egg masses of CRLFs.

Potential indirect effects to the CRLF based on impacts to habitat and/or primary production were assessed using RQs for aquatic freshwater non-vascular plants based on myclobutanil toxicity data. There is no freshwater vascular plant data for myclobutanil so risk is assessed qualitatively.

As previously discussed, acute RQs for aquatic non-vascular plants did not exceed the LOC of 1 for any of the assessed uses.

No aquatic vascular plant toxicity data are available for myclobutanil. As previously described, toxicity data from other conazoles were used to assess risk from myclobutanil. For the seven conazole fungicides evaluated, the range of 7/14-day EC_{50}s was 0.02 to 9.02 mg a.i./L and the mean was 1.84 mg a.i./L. Assuming that myclobutanil toxicity to aquatic vascular plants is similar to other conazoles, there were no exceedences of the LOC using the EC_{50} data from 6 of the 7 conazoles and the conazole mean EC_{50}. However, using the most sensitive endpoint (metconazole = 0.02 mg a.i./L), resulted in exceedences of the LOC of 1 for about one third of the myclobutanil use scenarios (RQs based on myclobutanil plus 1,2,4 triazole EECs ranged from 0.13 to 2.79). Metaconazole toxicity data suggests the possibility of effects from myclobutanil on aquatic vascular plants that may exceed the LOC. However, there is considerable uncertainty associated with extrapolating toxicity from other conazoles to myclobutanil, thus the effects of myclobutanil cannot be quantified without data on myclobutanil toxicity to aquatic vascular plants.

As previously discussed, available monitoring data show myclobutanil concentrations that are much lower than the modeled concentrations. There are no acceptable open literature data available or reported aquatic plant incidents attributed myclobutanil.

Based on the weight of evidence, there is minimal potential indirect impact to the CRLF (habitat effects) based on effects of myclobutanil on aquatic plants (vascular and non-vascular). The effects determination is may effect, not likely to adversely affect.

5.2.3.2 Terrestrial Plants

There are no registrant-submitted terrestrial plant toxicity data for myclobutanil for assessment of the potential for indirect effects to the aquatic- and terrestrial-phase CRLF via effects to riparian vegetation or effects to the primary constituent elements (PCEs) relevant to the aquatic- and terrestrial-phase CRLF. As stated previously, limited evidence in the open literature indicates that myclobutanil has the potential to elicit phototoxic effects. At 1.07 lbs a.i./A applied at 28-30 day intervals, there was evidence of decreased quality of “Tifgreen” Bermuda grass (ECOTOX ref. no. 76524). One incident report (I014702-074) indicated foliar necrosis and some defoliation with roses after exposure to myclobutanil. Damage varied from house to house and by rose variety. The certainty index for this incident (I014702-074) was possible. The application rate(s) were not reported for this incident.

Also stated previously, myclobutanil is a member of the class of triazole sterol 14α-demethylase-inhibitors (DMIs). To date, no other DMI triazole fungicides have been assessed for risk to the CRLF. However, terrestrial plant studies are available on 5 other DMI triazole fungicides that have at least one endpoint that may be used in the TerrPlant (v. 1.2.2) model for terrestrial plants. For risk description purposes, these endpoints were used in the model as surrogates for myclobutanil, using the solubility of myclobutanil for the potential runoff fraction. In general, using the endpoints from the other triazole DMI fungicides with the myclobutanil application rates, dicots living in semi-aquatic areas would be the most sensitive terrestrial plant species. The TerrPlant model was used to determine the myclobutanil application rates that would exceed the LOC for listed dicots and non-listed dicots inhabiting semi-aquatic areas for both aerial and ground applications. Table 5.11 summarizes these application rates.

Table 5.11 Myclobutanil Application Rates Combined with Endpoints from 5 Triazole DMI Fungicides Exceeding the Terrestrial Plant LOC for Listed and Non-Listed Dicots in Semi-Aquatic Areas

Triazole Fungicide	Application Rate (lbs a.i./A)			
	Non-listed dicots		Listed dicots	
	Aerial, Airblast, Spray Chemigation	Ground	Aerial, Airblast, Spray Chemigation	Ground
Cyproconazole	0.16	0.17	0.12	0.13
Metconazole	0.28	0.30	0.14	0.15
Propiconazole	0.33	0.36	0.10	0.11
Prothioconazole	Not available[1]	Not available[1]	0.05	0.06
Triticonazole	0.03	0.03	0.007	0.008

[1] No EC_{25} available

It is noted that the labeled uses of myclobutanil include direct application to a variety of terrestrial plants (agricultural and ornamental) at multiple growth stages (e.g., seed treatment, pre-bloom, bloom, foliar, post-bloom etc.). Considering the fact that the labels provide for exposure to terrestrial plants throughout the growth stage, it is probable that the damage to the crops is not so extensive to inhibit the use of this pesticide by applicators.

Nevertheless, due to the lack of terrestrial plant data and weight of the evidence from information provided in the open literature, incident data and the fact that surrogate data from similar fungicides would exceed the terrestrial plant LOC for many of the myclobutanil uses, it is determined that there is a potential of indirect impacts to the CRLF (habitat effects) based on effects of myclobutanil on terrestrial plants. The effects determination is likely to adversely affect.

5.2.4 Effects to Designated Critical Habitat

Risk conclusions for the designated critical habitat are the same as those for indirect effects.

5.2.4.1 Aquatic-Phase PCEs

Three of the four assessment endpoints for the aquatic-phase primary constituent elements (PCEs) of designated critical habitat for the CRLF are related to potential effects to aquatic and/or terrestrial plants:

- Alteration of channel/pond morphology or geometry and/or increase in sediment deposition within the stream channel or pond: aquatic habitat (including riparian vegetation) provides for shelter, foraging, predator avoidance, and aquatic dispersal for juvenile and adult CRLFs.

- Alteration in water chemistry/quality including temperature, turbidity, and oxygen content necessary for normal growth and viability of juvenile and adult CRLFs and their food source.
- Reduction and/or modification of aquatic-based food sources for pre-metamorphs (*e.g.*, algae).

Conclusions for potential indirect effects to the CRLF via direct effects to aquatic and terrestrial plants are used to determine whether effects to critical habitat may occur. There were no LOC exceedences for aquatic non-vascular plants (section 5.2.2.1). As stated previously, toxicity data from other conazole (triazole) fungicides were used to characterize risk to aquatic vascular plants, assuming that myclobutanil toxicity is similar to other conazoles due to similar mode of action (section 5.2.3.1). There were no exceedences of the LOC using the EC_{50} data from 6 of the 7 conazoles and the conazole mean EC_{50}. However, using the most sensitive endpoint resulted in exceedences of the LOC for about one third of the myclobutanil use scenarios. There are no registrant-submitted terrestrial plant toxicity data for myclobutanil. When the results of terrestrial plant studies conducted with five other triazole DMI fungicides are used with the application rates for myclobutanil in the Terrplant model, dicots living in semi-aquatic areas appear to be the most sensitive terrestrial plants, with potential exceedance of the terrestrial plant LOC for a variety of uses (section 5.2.3.2). Overall, there is a potential for effects to habitat via impacts to terrestrial plants.

The remaining aquatic-phase PCE is "alteration of other chemical characteristics necessary for normal growth and viability of CRLFs and their food source." This PCE is assessed by considering impacts to algae as food items for tadpoles and direct and indirect effects to the aquatic-phase CRLF via acute and chronic freshwater fish and invertebrate toxicity endpoints as measures of effects. There were no LOC exceedences for aquatic non-vascular plants, freshwater fish, or freshwater invertebrates (acute effects). No chronic freshwater invertebrate studies are available for myclobutanil. There are no exceedences of the freshwater invertebrate chronic LOC using toxicity data from 8 of 9 conazoles with similar mechanisms of toxicity. For the 9^{th} conazole, 2 chronic toxicity studies are available, one of which indicates LOC exceedances and the other does not. Overall, effects to habitat are not expected via alteration of other chemical characteristics necessary for normal growth and viability of CRLFs and their food source.

5.2.4.2 Terrestrial-Phase PCEs

Two of the four assessment endpoints for the terrestrial-phase PCEs of designated critical habitat for the CRLF are related to potential effects to terrestrial plants:

- Elimination and/or disturbance of upland habitat; ability of habitat to support food source of CRLFs: Upland areas within 200 ft of the edge of the riparian vegetation or drip line surrounding aquatic and riparian habitat that are comprised of grasslands, woodlands, and/or wetland/riparian plant species that provides the CRLF shelter, forage, and predator avoidance.

- Elimination and/or disturbance of dispersal habitat: Upland or riparian dispersal habitat within designated units and between occupied locations within 0.7 mi of each other that allow for movement between sites including both natural and altered sites which do not contain barriers to dispersal.

There are no registrant-submitted terrestrial plant toxicity data for myclobutanil for assessment of effects to the primary constituent elements (PCEs) relevant to the aquatic- and terrestrial-phase CRLF. As stated above, there is limited evidence in the open literature that myclobutanil has the potential to elicit phototoxic effects and one incident was reported in which myclobutanil may have caused some foliar necrosis and defoliation in roses. In addition, when the results of terrestrial plant studies conducted with five other triazole DMI fungicides are used with the application rates for myclobutanil in the TerrPlant model, dicots living in semi-aquatic areas appear to be the most sensitive terrestrial plants, with potential exceedance of the terrestrial plant LOC for a variety of uses. Therefore, there is a potential for effects to habitat via effects to terrestrial plants (Section 5.2.3.2).

The third terrestrial-phase PCE is "reduction and/or modification of food sources for terrestrial phase juveniles and adults." To assess the impact of myclobutanil on this PCE, acute and chronic toxicity endpoints for terrestrial invertebrates, mammals, and terrestrial-phase frogs are used as measures of effects. For terrestrial invertebrates, although there is an uncertainty associated with potential mortality for listed small terrestrial invertebrates following acute exposure, based on the lack of mortality in the honey bee study, the absence of adverse effects in four of the five available literature studies, and the fact that the mirid study showed no toxicity to nymphs, it was determined that although there may be an effect, it is not likely to adversely affect the terrestrial invertebrate prey base for the CRLF. For mammals, the acute listed species LOC and the chronic LOC are exceeded for multiple uses. For terrestrial-phase amphibians, using birds as a surrogate, there are acute LOC listed species exceedances for multiple uses. The chronic avian LOC is exceeded for turf and cotton uses. Therefore, there is a potential for effects to habitat via indirect effects to terrestrial-phase CRLFs via reduction in prey base (Sections 5.2.2.5 for mammals, and 5.2.2.6 for frogs).

The fourth terrestrial-phase PCE is based on alteration of chemical characteristics necessary for normal growth and viability of juvenile and adult CRLFs and their food source. Again, for terrestrial invertebrates, although there is an uncertainty associated with potential mortality for listed small terrestrial invertebrates following acute exposure, based on the lack of mortality in the honey bee study, the absence of adverse effects in four of the five available literature studies, and the fact that the mirid study showed no toxicity to nymphs, it was determined that although there may be an effect, it is not likely to adversely affect the terrestrial invertebrate prey base for the CRLF. For mammals, the acute listed species LOC and the chronic LOC are exceeded for multiple uses. For terrestrial-phase amphibians, using birds as a surrogate, there are acute LOC listed species exceedances for multiple uses. The chronic avian LOC is exceeded for turf and cotton uses. Therefore**,** there is a potential for effects to habitat via indirect effects (Sections 5.2.2.5 for mammals and 5.2.2.6 for frogs) to terrestrial-phase CRLFs.

5.2.5 Spatial Extent of Potential Effects

An LAA effects determination applies to those areas where it is expected that the pesticide's use will directly or indirectly affect the CRLF or its designated critical habitat. To determine this area, the footprint of myclobutanil's use pattern is identified, using land cover data that correspond to myclobutanil's use pattern. The spatial extent of the effects determination also includes areas beyond the initial area of concern that may be impacted by runoff and/or spray drift. The identified direct/indirect effects and/or effects to critical habitat are anticipated to occur only for those currently occupied core habitat areas, CNDDB occurrence sections, and designated critical habitat for the CRLF that overlap with the initial area of concern plus greater than 158 feet from its boundary. It is assumed that non-flowing waterbodies (or potential CRLF habitat) are included within this area.

In addition to the spray drift buffer, a downstream dilution extent analysis would normally be conducted that would result in a specified distance which would represent the maximum continuous distance of downstream dilution from the edge of the initial area of concern. This was not conducted for myclobutanil because all aquatic RQs with all modeled scenarios with myclobutanil and myclobutanil plus 1,2,4 triazole were lower that the related LOCs.

The determination of the buffer distance for spatial extent of the effects determination is described below.

5.2.5.1 Spray Drift

In order to determine terrestrial and aquatic habitats of concern due to myclobutanil exposures through spray drift, it is necessary to estimate the distance that spray applications can drift from the treated area and still be present at concentrations that exceed levels of concern. An analysis of spray drift distances was completed using AgDrift (v. 2.01).

Spatial analysis of spray drift effects is limited to consideration of a single application because, due to variable wind conditions, multiple applications are not likely to impact the same location each time. Spray drift distances depend on both application rate and method. The range of possible impacts was assessed by modeling uses with the highest and lowest single maximum application rate for each method of application that resulted in LOC exceedances. A turf grass use was modeled as the highest application rate for ground equipment. Mango and hops commodities were modeled as the highest rate for aerial application. A use on caneberries (e.g., boysenberry) was modeled for lowest single maximum application rate for both ground and aerial methods to represent a lower bound for potential impact.

Myclobutanil labels do not have specific application requirements for reducing potential spray drift, that is, restrictions on wind speed, release height and droplet size. Therefore, conservative Tier I AgDrift default values are used for these inputs (Table 5.12).

Table 5.12 Input Parameters for Simulation of Myclobutanil in Spray Drift Using AgDrift (v. 2.01)

Parameter Description	Turf Grass	Mango	Caneberry	Caneberry
Application Method	Ground	Aerial	Ground	Aerial
Application Rate	1.3	0.25	0.0625	0.0625
Droplet Size Distribution	Very Fine to Fine - 90^{th} Percentile			
Release Height	High Boom	NA	High Boom	NA

Table 5.13 includes uses with the maximum single application rates for each application method and presents a summary of the buffer distances at which spray drift deposition from these uses drop below levels of concern (e.g., RQs will be below LOCs). The estimated buffer distance identifies those locations where terrestrial landscapes can be impacted by spray drift deposition alone (no runoff considered). These distances represent the maximum extent where effects are possible using the most sensitive terrestrial data and, in the case of myclobutanil, the chronic LOC of 1. The terrestrial analysis is based on the rat reproduction study NOAEL of 16 mg/kg bw/day, the most sensitive terrestrial endpoint. Using this endpoint and the highest rates for both aerial and ground applications, the estimated maximum distance at which any LOC for terrestrial species may be exceeded is 158 feet from the treated area for aerial applications and 76 feet for ground applications. An analysis of potential risk to the aquatic-phase CRLF from spray drift was not conducted because no myclobutanil uses resulted in LOC exceedances for freshwater aquatic species.

Table 5.13 Summary of Maximum Predicted Distances for Potential Spray Drift Effects

Application Method	Application Rate (lb/ai Acre)	Uses	Terrestrial LD_{50} Distance (ft)
Aerial	0.5	Mango	158
	0.0625	Caneberries	0
Ground	1.3	Turf Grass	76
	0.0625	Caneberries	0

5.2.5.2 Downstream Dilution Analysis

Downstream dilution analysis is an approach used to estimate the downstream extent of exposure in streams and rivers where the EEC may be above levels that would exceed LOCs. As stated earlier, all aquatic RQs from all modeled scenarios with myclobutanil and myclobutanil plus 1,2,4 triazole were lower that the related LOCs. Therefore, given that no LOCs were exceeded, a downstream dilution analysis was not performed.

5.2.5.3 Overlap between CRLF habitat and Spatial Extent of Potential Effects

An LAA effects determination is made to those areas where it is expected that the pesticide's use will directly or indirectly affect the CRLF or its designated critical habitat and the area overlaps with the core areas, critical habitat and available occurrence data for CRLF.

For myclobutanil, the use pattern in the following land cover classes (cultivated crops, developed land (low, medium and high intensity and open space), forest, open water, orchards and vineyards, pasture/hay, wetlands, turf and rights-of-way) also includes areas beyond the initial area of concern that may be impacted by runoff and/or spray drift overlaps with CRLF habitat. When the footprint of the initial area of concern (which represents potential myclobutanil use sites) is compared to CRLF habitat, there are several areas of overlap (Figure 5.1). Appendix E provides maps of the initial area of concern, along with CRLF habitat areas, including currently occupied core areas, CNDDB occurrence sections, and designated critical habitat. It is expected that any additional areas of CRLF habitat that are located 158 ft (to account for offsite migration via spray drift) outside the initial area of concern may also be impacted and are part of the full spatial extent of the LAA/effects to critical habitat effects determination.

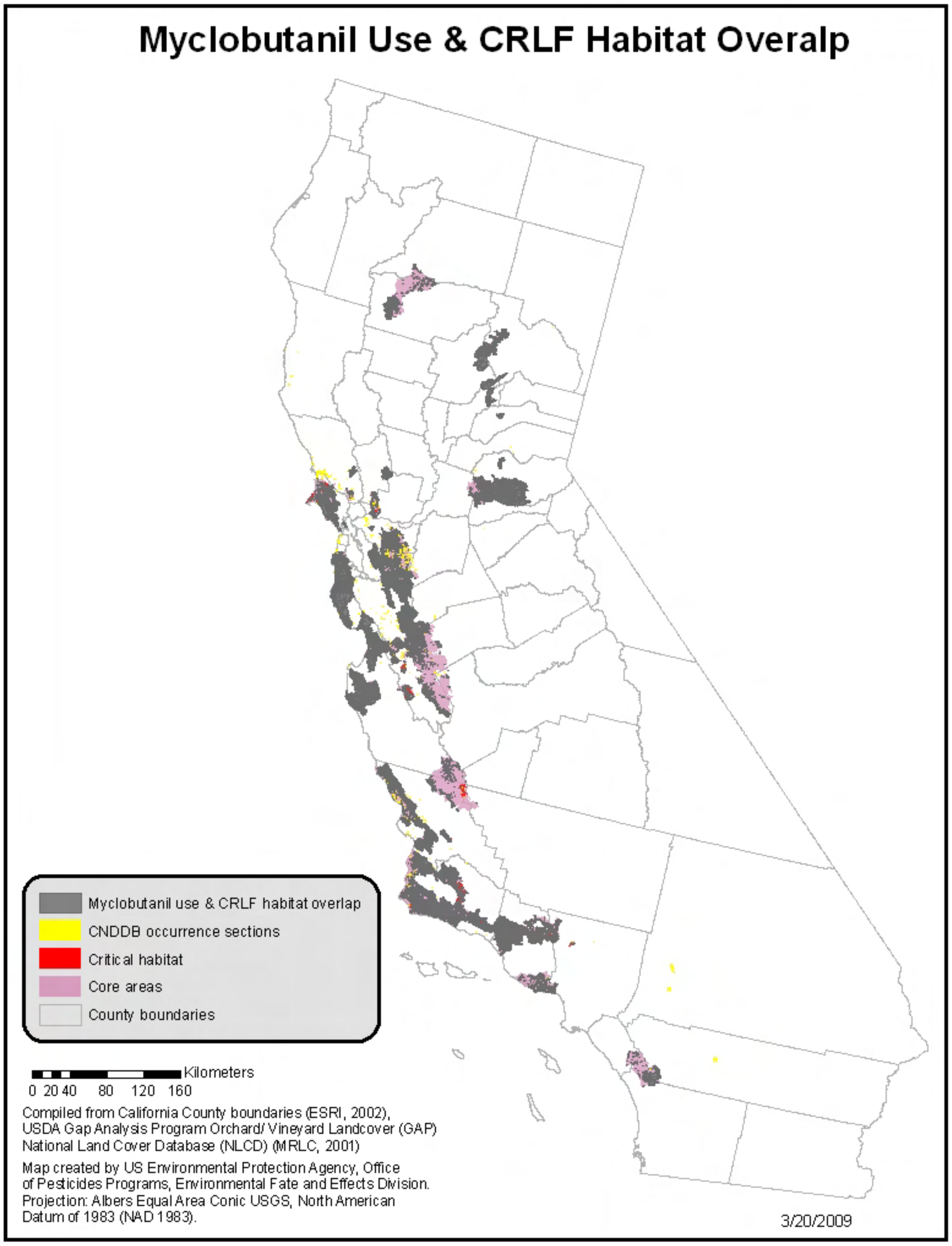

Figure 5.1 Overlap Map: CRLF Habitat and Myclobutanil Initial Area of Concern

6 Uncertainties

6.1 Exposure Assessment Uncertainties

6.1.1 Maximum Use Scenario

The screening-level risk assessment focuses on characterizing potential ecological risks resulting from a maximum use scenario, which is determined from labeled statements of maximum application rate and number of applications with the shortest time interval between applications. The frequency at which actual uses approach this maximum use scenario may be dependant on pest resistance, timing of applications, cultural practices, and market forces.

6.1.2 Aquatic Exposure Modeling of Myclobutanil

The standard ecological water body scenario (EXAMS pond) used to calculate potential aquatic exposure to pesticides is intended to represent conservative estimates, and to avoid underestimations of the actual exposure. The standard scenario consists of application to a 10-hectare field bordering a 1-hectare, 2-meter deep (20,000 m^3) pond with no outlet. Exposure estimates generated using the EXAMS pond are intended to represent a wide variety of vulnerable water bodies that occur at the top of watersheds including prairie pot holes, playa lakes, wetlands, vernal pools, man-made and natural ponds, and intermittent and lower order streams. As a group, there are factors that make these water bodies more or less vulnerable than the EXAMS pond. Static water bodies that have larger ratios of pesticide-treated drainage area to water body volume would be expected to have higher peak EECs than the EXAMS pond. These water bodies will be either smaller in size or have larger drainage areas. Smaller water bodies have limited storage capacity and thus may overflow and carry pesticide in the discharge, whereas the EXAMS pond has no discharge. As watershed size increases beyond 10-hectares, it becomes increasingly unlikely that the entire watershed is planted with a single crop that is all treated simultaneously with the pesticide. Headwater streams can also have peak concentrations higher than the EXAMS pond, but they likely persist for only short periods of time and are then carried and dissipated downstream.

The Agency acknowledges that there are some unique aquatic habitats that are not accurately captured by this modeling scenario and modeling results may, therefore, under- or over-estimate exposure, depending on a number of variables. For example, aquatic-phase CRLFs may inhabit water bodies of different size and depth and/or are located adjacent to larger or smaller drainage areas than the EXAMS pond. The Agency does not currently have sufficient information regarding the hydrology of these aquatic habitats to develop a specific alternate scenario for the CRLF. CRLFs prefer habitat with perennial (present year-round) or near-perennial water and do not frequently inhabit vernal (temporary) pools because conditions in these habitats are generally not suitable (Hayes and Jennings 1988). Therefore, the EXAMS pond is assumed to be representative of exposure to aquatic-phase CRLFs. In addition, the Services agree that the existing EXAMS pond represents the best currently available approach for estimating aquatic exposure to pesticides (USFWS/NMFS 2004).

In general, the linked PRZM/EXAMS model produces estimated aquatic concentrations that are expected to be exceeded once within a ten-year period. The Pesticide Root Zone Model is a process or "simulation" model that calculates what happens to a pesticide in an agricultural field on a day-to-day basis. It considers factors such as rainfall and plant transpiration of water, as well as how and when the pesticide is applied. It has two major components: hydrology and chemical transport. Water movement is simulated by the use of generalized soil parameters, including field capacity, wilting point, and saturation water content. The chemical transport component can simulate pesticide application on the soil or on the plant foliage. Dissolved, adsorbed, and vapor-phase concentrations in the soil are estimated by simultaneously considering the processes of pesticide uptake by plants, surface runoff, erosion, decay, volatilization, foliar wash-off, advection, dispersion, and retardation.

Uncertainties associated with each of these individual components add to the overall uncertainty of the modeled concentrations. Additionally, model inputs from the environmental fate degradation studies are chosen to represent the upper confidence bound on the mean values that are not expected to be exceeded in the environment approximately 90 percent of the time. Mobility input values are chosen to be representative of conditions in the environment. The natural variation in soils adds to the uncertainty of modeled values. Factors such as application date, crop emergence date, and canopy cover can also affect estimated concentrations, adding to the uncertainty of modeled values. Factors within the ambient environment such as soil temperatures, sunlight intensity, antecedent soil moisture, and surface water temperatures can cause actual aquatic concentrations to differ for the modeled values.

Unlike spray drift, tools are currently not available to evaluate the effectiveness of a vegetative setback on runoff and loadings. The effectiveness of vegetative setbacks is highly dependent on the condition of the vegetative strip. For example, a well-established, healthy vegetative setback can be a very effective means of reducing runoff and erosion from agricultural fields. Alternatively, a setback of poor vegetative quality or a setback that is channelized can be ineffective at reducing loadings. Until such time as a quantitative method to estimate the effect of vegetative setbacks on various conditions on pesticide loadings becomes available, the aquatic exposure predictions are likely to overestimate exposure where healthy vegetative setbacks exist and underestimate exposure where poorly developed, channelized, or bare setbacks exist.

In order to account for uncertainties associated with modeling, available monitoring data were compared to PRZM/EXAMS estimates of peak EECs for the different uses. As discussed above, several data values were available from NAWQA for myclobutanil, but not the 1,2,4-triazole degradate, concentrations measured in surface waters receiving runoff from agricultural areas. The specific use patterns (e.g. application rates and timing, crops) associated with the agricultural areas are unknown, however, they are assumed to be representative of potential myclobutanil use areas. The 1-in-10 year peak, and 21 and 60-day running mean concentrations (EECs) for myclobutanil and myclobutanil plus 1,2,4-triazole estimated by PRZM/EXAMS were all higher than the highest myclobutanil concentration observed in the USGS NAWQA (0.51 µg/L) monitoring data. The peak myclobutanil plus 1,2, 4-triazole concentrations ranged between 5.1 and 61.4 µg/L; the 21-day means ranged from 15.1 to 61.2 µg/L and the 60-day mean ranged from 5.08 to 60.7 µg/L, respectively. There are no detections of myclobutanil report in ground water in the NAQWA studies.

Based upon the vapor pressure and Henry's Law Constant, the transport of myclobutanil in the atmosphere vapor phase would not be expected. However, myclobutanil residues have been detected in rain water. The study by Vogel et al., 2008 attributed the myclobutanil to almonds. It is assumed that the reason for the detections are because fungicides are typically applied to almonds trees my air blast or aerial spray (Mosz, 2002) or that the myclobutanil is sorbed to wind blow soil particles.

6.1.3 Usage Uncertainties

County-level usage data were obtained from California's Department of Pesticide Regulation Pesticide Use Reporting (CDPR PUR) database. Four years of data (2002 – 2005) were included in this analysis because statistical methodology for identifying outliers, in terms of area treated and pounds applied, was provided by CDPR for these years only. No methodology for removing outliers was provided by CDPR for 2001 and earlier pesticide data; therefore, this information was not included in the analysis because it may misrepresent actual usage patterns. CDPR PUR documentation indicates that errors in the data may include the following: a misplaced decimal; incorrect measures, area treated, or units; and reports of diluted pesticide concentrations. In addition, it is possible that the data may contain reports for pesticide uses that have been cancelled. The CPDR PUR data does not include home owner applied pesticides; therefore, residential uses are not likely to be reported. As with all pesticide usage data, there may be instances of misuse and misreporting. The Agency made use of the most current, verifiable information; in cases where there were discrepancies, the most conservative information was used.

6.1.4 Terrestrial Exposure Modeling of Myclobutanil

The Agency relies on the work of Fletcher et al. (1994) for setting the assumed pesticide residues in wildlife dietary items. These residue assumptions are believed to reflect a realistic upper-bound residue estimate, although the degree to which this assumption reflects a specific percentile estimate is difficult to quantify. It is important to note that the field measurement efforts used to develop the Fletcher estimates of exposure involve highly varied sampling techniques. It is entirely possible that much of these data reflect residues averaged over entire above ground plants in the case of grass and forage sampling.

It was assumed that ingestion of food items in the field occurs at rates commensurate with those in the laboratory. Although the screening assessment process adjusts dry-weight estimates of food intake to reflect the increased mass in fresh-weight wildlife food intake estimates, it does not allow for gross energy differences. Direct comparison of a laboratory dietary concentration- based effects threshold to a fresh-weight pesticide residue estimate would result in an underestimation of field exposure by food consumption by a factor of 1.25 – 2.5 for most food items.

Differences in assimilative efficiency between laboratory and wild diets suggest that current screening assessment methods do not account for a potentially important aspect of food requirements. Depending upon species and dietary matrix, bird assimilation of wild diet energy ranges from 23 – 80%, and mammal's assimilation ranges from 41 – 85% (U.S. Environmental Protection Agency, 1993). If it is assumed that laboratory chow is formulated to maximize assimilative efficiency (e.g., a value of 85%), a potential for underestimation of exposure may exist by assuming that consumption of food in the wild is comparable with consumption during laboratory testing. In the screening process, exposure may be underestimated because metabolic rates are not related to food consumption.

For the terrestrial exposure analysis of this risk assessment, a generic bird or mammal was assumed to occupy either the treated field or adjacent areas receiving a treatment rate on the field. Actual habitat requirements of any particular terrestrial species were not considered, and it was assumed that species occupy, exclusively and permanently, the modeled treatment area. Spray drift model predictions suggest that this assumption leads to an overestimation of exposure to species that do not occupy the treated field exclusively and permanently.

6.1.5 Spray Drift Modeling

Although there may be multiple myclobutanil applications at a single site, it is unlikely that the same organism would be exposed to the maximum amount of spray drift from every application made. In order for an organism to receive the maximum concentration of myclobutanil from multiple applications, each application of myclobutanil would have to occur under identical atmospheric conditions (*e.g.*, same wind speed and – for plants – same wind direction) and (if it is an animal) the animal being exposed would have to be present directly downwind at the same distance after each application. Although there may be sites where the dominant wind direction is fairly consistent (at least during the relatively quiescent conditions that are most favorable for aerial spray applications), it is nevertheless highly unlikely that plants in any specific area would receive the maximum amount of spray drift repeatedly. It appears that in most areas (based upon available meteorological data) wind direction is temporally very changeable, even within the same day. Additionally, other factors, including variations in topography, cover, and meteorological conditions over the transport distance are not accounted for by the AgDRIFT model (*i.e.*, it models spray drift from aerial and ground applications in a flat area with little to no ground cover and a steady, constant wind speed and direction). Therefore, in most cases, the drift estimates from AgDRIFT may overestimate exposure even from single applications, especially as the distance increases from the site of application, since the model does not account for potential obstructions (*e.g.*, large hills, berms, buildings, trees, *etc*.). Furthermore, conservative assumptions are often made regarding the droplet size distributions being modeled (e.g.: 'ASAE Very Fine to Fine' for all uses), the application method (*e*.g., aerial), release heights and wind speeds. Alterations in any of these inputs would change the area of potential effect.

6.2 Effects Assessment Uncertainties

6.2.1 Age Class and Sensitivity of Effects Thresholds

It is generally recognized that test organism age may have a significant impact on the observed sensitivity to a toxicant. The acute toxicity data for fish are collected on juvenile fish between 0.1 and 5 grams. Aquatic invertebrate acute testing is performed on recommended immature age classes (e.g., first instar for daphnids, second instar for amphipods, stoneflies, mayflies, and third instar for midges).

Testing of juveniles may overestimate toxicity at older age classes for pesticide active ingredients that act directly without metabolic transformation because younger age classes may not have the enzymatic systems associated with detoxifying xenobiotics. In so far as the available toxicity data may provide ranges of sensitivity information with respect to age class, this assessment uses the most sensitive life-stage information as measures of effect for surrogate aquatic animals, and is therefore, considered as protective of the CRLF.

6.2.2 Use of Surrogate Species Effects Data

Guideline toxicity tests and open literature data on myclobutanil are not available for frogs or any other aquatic-phase amphibian; therefore, freshwater fish are used as surrogate species for aquatic-phase amphibians. Endpoints based on freshwater fish ecotoxicity data are assumed to be protective of potential direct effects to aquatic-phase amphibians including the CRLF, and extrapolation of the risk conclusions from the most sensitive tested species to the aquatic-phase CRLF is likely to overestimate the potential risks to those species. Efforts are made to select the organisms most likely to be affected by the type of compound and usage pattern; however, there is an inherent uncertainty in extrapolating across phyla. In addition, the Agency's LOCs are intentionally set very low, and conservative estimates are made in the screening level risk assessment to account for these uncertainties.

6.2.3 Sublethal Effects

When assessing acute risk, the screening risk assessment relies on the acute mortality endpoint as well as a suite of sublethal responses to the pesticide, as determined by the testing of species response to chronic exposure conditions and subsequent chronic risk assessment. Consideration of additional sublethal data in the effects determination t is exercised on a case-by-case basis and only after careful consideration of the nature of the sublethal effect measured and the extent and quality of available data to support establishing a plausible relationship between the measure of effect (sublethal endpoint) and the assessment endpoints. However, the full suite of sublethal effects from valid open literature studies is considered for the purposes of defining the action area.

No sublethal effects related to this assessment were available in the open literature. To the extent to which sublethal effects are not considered in this assessment, the potential direct and indirect effects of myclobutanil on CRLF may be underestimated.

6.2.4 Location of Wildlife Species

For the terrestrial exposure analysis of this risk assessment, a generic bird or mammal was assumed to occupy either the treated field or adjacent areas receiving a treatment rate on the field. Actual habitat requirements of any particular terrestrial species were not considered, and it was assumed that species occupy, exclusively and permanently, the modeled treatment area. Spray drift model predictions suggest that this assumption leads to an overestimation of exposure to species that do not occupy the treated field exclusively and permanently.

6.2.5 Use of Surrogate Chemical Effects Data

Guideline toxicity tests and open literature data on myclobutanil were not available for aquatic invertebrate (chronic exposure), aquatic vascular plants, or terrestrial plants. In lieu of any myclobutanil data, toxicity data from other conazole (DMI triazole) fungicides were used to characterize risk, assuming that myclobutanil toxicity is similar to other conazoles due to similar mode of action. In so far as data from other conazoles provides a range of sensitivity for conazole fungicides, there is considerable uncertainty associated with extrapolating toxicity from other conazoles to myclobutanil. Thus, the effects of myclobutanil cannot be quantified without data on myclobutanil toxicity to aquatic invertebrates, aquatic vascular plants, and terrestrial plants.

7 Risk Conclusions

In fulfilling its obligations under Section 7(a)(2) of the Endangered Species Act, the information presented in this endangered species risk assessment represents the best data currently available to assess the potential risks of myclobutanil to the CRLF and its designated critical habitat.

Based on the best available information, the Agency makes a "Likely to Adversely Affect" determination for the CRLF from the use of myclobutanil. The Agency has also determined that there is the potential for effects to CRLF designated critical habitat from the use of the chemical. The CRLF and/or its critical habitat may be affected for all uses.

This assessment indicates that direct effects to the terrestrial-phase CRLF eating small herbivorous mammals on a dose-basis may be at risk following acute exposure to myclobutanil at application rates of 0.12 lb a.i./A and above (most crops and turf; cotton seed treatment). In addition, the terrestrial-phase CRLF eating small invertebrates on a dietary basis may be at risk for direct effects following chronic exposure to myclobutanil applied to cotton (0.06 lb a.i./cwt) and turf at 1.3 lbs a.i./A. Direct effects on the aquatic-phase CRLF are not expected.

Indirect effects to the terrestrial-phase CRLF, based on reduction in prey base may occur with terrestrial phase amphibians on a dose-basis following acute exposure at application rates of 0.12 lb a.i./A and above (most crops, cotton and turf) and on a dietary-basis following chronic exposure at an application rate of 1.3 lbs a.i./A (turf) and when applied to cotton (0.06 lb a.i./cwt). Indirect effects (reduction in prey base) may also occur with mammals following acute exposure on a dose-basis at application rates of 0.25 lb a.i./A and above (apple, apricot, cherry, nectarine, peach, hops and turf uses) and chronic exposure on a dose-basis at application rates of 0.0625 lbs a.i./A and above (e.g., all uses) and on a dietary-basis of 0.25 lbs a.i./A and above (apples, apricots, cherries, nectarines, peaches, cotton and turf). Indirect effects to the aquatic-phase CRLF, based on reduction in prey base are not expected. Minimal potential indirect impact to the CRLF via effects of myclobutanil on terrestrial invertebrate food items is expected. No effects were observed with aquatic non-vascular plants and with aquatic invertebrates following acute exposure. No chronic data are available for aquatic invertebrates. The weight of the evidence, including chronic data from similar conazole pesticides indicates that although myclobutanil may affect the aquatic invertebrate population following chronic exposure, it is not expected to adversely affect the population.

Indirect effects to both the aquatic- and terrestrial-phase CRLF based on aquatic and riparian habitat, cover and/or primary productivity (e.g., effects on aquatic and terrestrial plants) may occur due to potential effects on the riparian terrestrial plant community. As stated previously, no effects were observed with aquatic non-vascular plants. No data are available for either aquatic vascular or terrestrial plants. For aquatic vascular plants, the weight of the evidence, including plant data from similar conazole pesticides indicates that although there may be effects with some of the registered myclobutanil uses, adverse affects are not expected. For terrestrial plants, weight of the evidence from information provided in the open literature, incident data and the fact that surrogate data from similar fungicides would exceed the terrestrial plant LOC for many of the myclobutanil uses, it is determined that effects to terrestrial plants may affect the CRLF via habitat effects. Based on potential effects to the avian/terrestrial-phase amphibian, mammalian and terrestrial plant populations, there is a potential for habitat effects associated with all 4 of the terrestrial-phase PCE's: elimination and/or disturbance of upland habitat and ability of habitat to support food source of CRLFs, elimination and/or disturbance of dispersal habitat, reduction and/or modification of food sources for terrestrial phase juveniles and adults and alteration of chemical characteristics necessary for normal growth and viability of juvenile and adult CRLFs and their food source.

Given the LAA determination for the CRLF and potential effects to designated critical habitat, a description of the baseline status and cumulative effects for the CRLF is provided in Attachment 2.

The LAA effects determination applies to those areas where it is expected that the pesticide's use will directly or indirectly affect the CRLF or its designated critical habitat. To determine this area, the footprint of myclobutanil's use pattern is identified, using corresponding land cover data. The spatial extent of the LAA effects determination also includes areas beyond the initial area of concern that may be impacted by runoff and/or spray drift. The identified direct and indirect effects and/or effects to critical habitat are anticipated to occur only for those currently occupied core habitat areas, CNDDB occurrence sections, and designated critical habitat for the CRLF that overlap with the initial area of concern plus 158 feet from its boundary (see Section 5.1.4 for further analysis). It is assumed that non-flowing waterbodies (or potential CRLF habitat) are included within this area.

Appendix E provides maps of the initial area of concern, along with CRLF habitat areas, including currently occupied core areas, CNDDB occurrence sections, and designated critical habitat. It is expected that any additional areas of CRLF habitat that are located 158 ft (to account for offsite migration via spray drift) outside the initial area of concern may also be impacted and are part of the full spatial extent of the LAA/effects to critical habitat determination.

A summary of the risk conclusions and effects determinations for the CRLF and its critical habitat, given the uncertainties discussed in Section 6, is presented in Table 7.1 and Table 7.2.

Table 7.1 Effects Determination Summary for Myclobutanil Use and the CRLF

Assessment Endpoint	Effects Determination [1]	Basis for Determination
Survival, growth, and/or reproduction of CRLF individuals	LAA[1]	**Potential for Direct Effects**
		Aquatic-phase (Eggs, Larvae, and Adults): Acute and chronic freshwater fish RQs are below the respective level of concern (LOC) for all uses of myclobutanil.
		Terrestrial-phase (Juveniles and Adults): The acute avian LOC is exceeded at application rates of 0.12 lb a.i./A and above (most crops, cotton and turf). The highest probabilities of an individual effect range from 1 in ~ 3.88E+02 to 1 in ~ 1. The chronic avian LOC is exceeded following uses on cotton (0.06 lb a.i./cwt) and turf at 1.3 lbs a.i./A. Myclobutanil uses overlap CRLF habitat.
		Potential for Indirect Effects
		Aquatic prey items, aquatic habitat, cover and/or primary productivity Acute and chronic freshwater fish RQs are below the respective LOC for all uses of myclobutanil.

Assessment Endpoint	Effects Determination [1]	Basis for Determination
		Acute freshwater invertebrate RQs are below the LOC for all uses of myclobutanil. No chronic freshwater invertebrate studies are available for myclobutanil. Weight of the evidence from RQs based on myclobutanil EECs and toxicity data from 9 other conazole fungicides indicates that minimal impact is expected from chronic exposure to freshwater invertebrates as prey items. Acute RQs for aquatic non-vascular plants for all uses of myclobutanil are below the LOC. No aquatic vascular plant studies are available. Weight of the evidence from RQs based on myclobutanil EECs and toxicity data from 7 other conazole fungicides indicates minimal impact to the CRLF aquatic habitat, cover and/or primary productivity.
		Terrestrial prey items, riparian habitat See description above for direct effects on birds as surrogate for terrestrial phase amphibians. LOCs for listed mammals exceeded following acute exposure at application rates of 0.25 lb a.i./A and above and chronic exposure on at application rates of 0.0625 lbs a.i./A and above. Percent effect on mammalian population is estimated to range from 4 – 42% for the myclobutanil uses. Myclobutanil uses overlap CRLF habitat. For terrestrial invertebrates, the honeybee acute contact data show no mortalities at concentration levels up to and including 2836 ppm (highest level tested), which is higher than highest dietary-based EEC for small insects with the use on turf; however, there is some uncertainty for potential mortality. For large invertebrates, there is no concern. Based on the results of the honey bee study and weight of the evidence from open literature studies, indirect impact to the CRLF via effects of myclobutanil on terrestrial invertebrate food items is expected to be minimal. No acceptable terrestrial plant studies are available. RQs based on EECs and toxicity data from 5 other conazole fungicides indicate that most uses may affect terrestrial plants, particularly dicots in semi-aquatic areas. Weight of the evidence from these data, the open literature and incident reports indicates that these effects may have an impact on riparian habitat.

[1] No effect (NE); May affect, but not likely to adversely affect (NLAA); May affect, likely to adversely affect (LAA)

Table 7.2 Effects Determination Summary for Myclobutanil Use and CRLF Critical Habitat Impact Analysis

Assessment Endpoint	Effects Determination	Basis for Determination
Modification of aquatic-phase PCE	Habitat Effects	Acute RQs for aquatic non-vascular plants for all uses of myclobutanil are below the LOC. No aquatic vascular plant studies are available. Weight of the evidence from RQs based on myclobutanil EECs and toxicity data from 7 other conazole fungicides indicates minimal impact to the CRLF aquatic habitat. No acceptable terrestrial plant studies are available. RQs based on EECs and toxicity data from 5 other conazole fungicides indicate that most uses may affect

Assessment Endpoint	Effects Determination	Basis for Determination
		terrestrial plants, particularly dicots in semi-aquatic areas. Weight of the evidence from these data, the open literature and incident reports indicates that these effects may have an impact on riparian habitat. Acute and chronic freshwater fish RQs are below the respective level of concern (LOC) for all uses of myclobutanil. Indirect effects to the CRLF through effects to its prey in the aquatic habitat (freshwater invertebrates) are expected to be minimal (see table 1.1).
Modification of terrestrial-phase PCE		No acceptable terrestrial plant studies are available. RQs based on EECs and toxicity data from 5 other conazole fungicides indicate that most uses may affect terrestrial plants, particularly dicots in semi-aquatic areas. Weight of the evidence from these data, the open literature and incident reports indicates that these effects may have an impact on riparian habitat. The acute avian LOC is exceeded at application rates of 0.12 lb a.i./A and above (most crops, cotton and turf). The chronic avian LOC is exceeded following uses on cotton (0.06 lb a.i./cwt) and turf at 1.3 lbs a.i./A. LOCs for listed mammals exceeded following acute exposure on a dose-basis for many crops and chronic exposure on a dose-basis for all uses and on a dietary-basis for many crops. For terrestrial invertebrates, the weight of the evidence indicates that minimal potential indirect impact to the CRLF via effects on terrestrial invertebrate food items is expected.

Based on the conclusions of this assessment, a formal consultation with the U. S. Fish and Wildlife Service under Section 7 of the Endangered Species Act should be initiated.

When evaluating the significance of this risk assessment's direct/indirect and habitat effects determinations, it is important to note that pesticide exposures and predicted risks to the species and its resources (i.e., food and habitat) are not expected to be uniform across the action area. In fact, given the assumptions of drift and downstream transport (i.e., attenuation with distance), pesticide exposure and associated risks to the species and its resources are expected to decrease with increasing distance away from the treated field or site of application. Evaluation of the implication of this non-uniform distribution of risk to the species would require information and assessment techniques that are not currently available. Examples of such information and methodology required for this type of analysis would include the following:

- Enhanced information on the density and distribution of CRLF life stages within specific recovery units and/or designated critical habitat within the action area. This information would allow for quantitative extrapolation of the present risk assessment's predictions of individual effects to the proportion of the population extant within geographical areas where those effects are predicted. Furthermore, such population information would allow for a more comprehensive evaluation of the significance of potential resource impairment to individuals of the species.

- Quantitative information on prey base requirements for individual aquatic- and terrestrial-phase frogs. While existing information provides a preliminary picture of the types of food sources utilized by the frog, it does not establish minimal requirements to sustain healthy individuals at varying life stages. Such information could be used to establish biologically relevant thresholds of effects on the prey base, and ultimately establish geographical limits to those effects. This information could be used together with the density data discussed above to characterize the likelihood of adverse effects to individuals.

- Information on population responses of prey base organisms to the pesticide. Currently, methodologies are limited to predicting exposures and likely levels of direct mortality, growth or reproductive impairment immediately following exposure to the pesticide. The degree to which repeated exposure events and the inherent demographic characteristics of the prey population play into the extent to which prey resources may recover is not predictable. An enhanced understanding of long-term prey responses to pesticide exposure would allow for a more refined determination of the magnitude and duration of resource impairment, and together with the information described above, a more complete prediction of effects to individual frogs and potential effects to critical habitat.

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